



## Appendix 3-1

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# Ecological Soil Screening Level Guidance - Draft

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*Plant and Soil Invertebrate Standard Operating Procedure # 3:  
Literature Evaluation and Data Extraction*

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*June 27, 2000*

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## **1.0 INTRODUCTION**

This standard operating procedure (SOP) describes how nine criteria are used for assessing the applicability of published studies for deriving Eco-SSLs and provides a set of rules for extracting and reporting the most appropriate study data. Only those studies that meet the Literature Acceptance Criteria in SOP 1 (Exhibit 3.1) should be evaluated and scored using this SOP. This SOP is intended to ensure that the data most appropriate for deriving an Eco-SSL are selected and used.

## **2.0 EVALUATION AND SCORING OF STUDY ATTRIBUTES**

Nine evaluation criteria are used to score each reported study (Attachment A). Scoring is based on a three-point scale: 0, 1, or 2, with 2 being the highest score indicating complete agreement with the criterion. The scores for each criteria are recorded in a Score Sheet spreadsheet (Attachment B) and summed to generate a total score for each study.

The user should recognize that toxicity studies reported in published literature were not conducted or intended for the purpose of deriving Eco-SSLs. Therefore, the specific information addressed by each criterion may not be reported for each study. Scoring should be objective however, in some instances, professional judgement may be needed to ascertain the appropriate score for a criterion.

Some publications will contain the results of several different studies; report toxicity data for more than one species or soil type (e.g., different soil pH, or percent organic matter). Each study should be scored separately. Studies that vary other parameters, such as temperature, photoperiod, or species life stage (e.g., immature versus mature), should not be considered different studies for the purpose of deriving an Eco-SSL.

When multiple studies are presented in a paper, the reviewer should assign a unique identification code to each study, and document information for each study separately on the Score Sheet. For example, a publication by Jones et al. (Identification No.1022) contains results for three separate experimental designs. In this example, results of each experimental design (i.e., study) should be evaluated and scored separately, and identified on the Score Sheets with unique identification code such as 1022a, 1022b, and 1022c.

A publication may include some studies that do not pass the Literature Acceptance Criteria. The reviewer should only score those individual studies that meet the requirements of the Literature Acceptance Criteria (see Exhibit 3.1). For example, if a study reports the results of both a topical application and artificial soil study, the topical application study (which does not meet the Literature Acceptance Criteria) would not be scored. Reviewers should provide comments on which studies were scored and which were excluded. These comments should be entered in the “comment” field of the Critical Notes form.

### 3.0 DATA EXTRACTION

For each study reviewed, a set of Critical Notes (Figure 1) are recorded on the Critical Notes spreadsheet (Attachment C). As with the Score Sheet, individual studies are assigned separate identification codes.

Details on the soil parameters including soil pH and percent organic matter (OM) are recorded. If a study reports the pH at both test initiation and completion, only the initial pH should be recorded. If a pH range is reported, the arithmetic mean of the minimum and maximum should be calculated and reported. However, if a range is reported and it includes a pH value that is outside of the acceptable soil parameters (i.e., pH < 4 or > 8.5), this study should be rejected and this information should be noted in the comment field of the Critical Notes.

If percent organic matter (%OM) is reported as a range for a single soil type and the range extends outside of the acceptable range (i.e., >10%), the study should be rejected and not used for deriving an Eco-SSL. This information should be noted in the comment field of the Critical Notes.

The evaluation criteria (Section 2.0) are used to develop a total score for each paper, which is recorded on the Critical Notes. The bioavailability score (Criterion #1), based on soil pH and % OM, is recorded separately.

Toxicity values are reported on the Critical Notes. Toxicity values are chemical concentrations related to measurements of an ecologically relevant endpoint (ERE). The EREs are defined in Table 1. Toxicity values should be reported on the basis of milligram per kilogram (mg/kg) dry weight of the chemical. If the concentrations are reported in units other than mg/kg, or are reported as the concentration of a salt, the reviewer should convert these values to mg/kg of the chemical and record the converted values on the Critical Notes. Any calculations or assumptions by the reviewer must be noted in the comment field of the Critical Notes. If the toxicity value is reported as a range of concentrations rather than a point estimate, no value should be recorded on the Critical Notes and the reason for not recording the toxicity values should be provided in the comment field.

Toxicity values are recorded on the Critical Notes according to toxicity parameter. Toxicity parameters are standard measurements of dose-response relationships. Acceptable toxicity parameters include

**Figure 1. Critical Notes**

- Identification code
- First author and year of publication
- Common name
- Species name
- Soil pH
- Percent organic matter (OM)
- Bioavailability score
- Total evaluation score
- Ecologically relevant endpoint (ERE)
- Preferred toxicity parameter
- Preferred toxicity value
- Secondary toxicity parameter
- Secondary toxicity value
- Other available toxicity parameters and concentrations
- Preference level
- Comments

NOAEC, LOAEC, EC<sub>10-19</sub>, EC<sub>20</sub>, and EC<sub>21-50</sub>. For deriving Eco-SSL, LC<sub>x</sub> and EC<sub><10</sub> are not acceptable toxicity parameters, however, if these are the only parameters reported for a study this information should be recorded in the comment field.

<b>Table 1. Ecologically Relevant Endpoints (ERE) and Definitions for Eco-SSL</b>	
<b>Ecologically Relevant Effects</b>	<b>Definition</b>
<b>REP</b>	<b>Reproduction:</b> measures of the effect of toxicants on the number of offsprings. Examples of EREs associated with reproduction include changes fecundity, number of progeny produced (births, eggs, cocoons, seeds, ramets), rate of reproduction (birth rates, hatching rates, etc.), rate of maturation, sexual development, clitella development, change in sex expression, and sterility number or proportion of abnormal progeny.
<b>POP</b>	<b>Population:</b> measurements and endpoints regarding a group of animals or plants of the same species occupying the same area at a given time. Measurement includes population dynamics. Examples of EREs associated with population include changes in size and age class structures, changes in sex ratio, intrinsic population growth rate, survivability of subsequent generations, diversity, evenness, index to population size (count, number, abundance), life table data, and population density (number/area), primary productivity, standing crop biomass.
<b>GRO</b>	<b>Growth:</b> a broad category which encompasses measures of weight and length. Examples of EREs associated with growth and development responses include change in body weight/length, seedling emergence, shoot length/growth, root elongation/growth, wet or dry mass, and yield.
<b>PHY (plants only)</b>	<b>Physiological:</b> for the purposes of developing Eco-SSLs, only plant studies will have EREs associated with physiological responses. Physiological endpoints for plants include net photosynthesis (CO <sub>2</sub> uptake, oxygen release), changes in chlorophyll content, chlorophyll fluorescence, deformation, membrane damage, desiccation/change in water content, dormancy measures, change in flowering, changes in senescence.

If the publication does not identify acceptable toxicity parameters, but sufficient data are provided, the reviewer should record the toxicity values under the appropriate toxicity parameters. For example, if a study does not identify LOAECs and NOAECs but they report treatments with and without a significant adverse effects, the reviewer should record these toxicity values as LOAECs and NOAECs and note in the comment field that these toxicity parameters were assigned.

If a study reports more than one toxicity value for the same type of toxicity parameter, a preferred toxicity value is selected according to the following hierarchy of EREs:

**Reproduction (REP) > Population (POP) > Growth (GRO) > Physiology (PHY)(plants only)**

If a publication reports multiple “preferred” toxicity values for the same study (e.g., two reproductive EC<sub>20</sub> values), the lowest value is recorded on the Critical Notes.

For each study that provides NOAEC and LOAEC values, these data are used to calculate a Maximum Acceptable Threshold Concentration (MATC). The MATC is the geometric mean of the NOAEC and LOAEC values:

$$GM = \exp(\text{average}(\ln Y_1, Y_2, Y_3 \dots Y_n))$$

A preference level (A - D) is calculated for each study using the Preference Level Table (Table 2) and recorded on the critical notes form. Preference level is determined by a study’s toxicity parameter and bioavailability score. Preference is given to studies that have higher bioavailability scores and more sensitive toxicity parameters.

Table 2. Preference Levels for Toxicity Data		
Level	Toxicity Parameter*	Bioavailability Score
<b>A</b>	EC <sub>20</sub> , EC <sub>10 - 19</sub> , MATC	2
<b>B</b>	EC <sub>20</sub> , EC <sub>10 - 19</sub> , MATC	1 or 2
<b>C</b>	EC <sub>20</sub> , EC <sub>10 - 19</sub> , MATC	0, 1, or 2
<b>D</b>	EC <sub>20</sub> , EC <sub>10 - 19</sub> , MATC, EC <sub>21 - 50</sub>	0, 1, or 2

EC<sub>xx</sub> = Effect Concentration for defined percentages of the population (i.e., 20%, 10-19%, 21-50%), MATC = Maximum Acceptable Threshold Concentration or the geometric mean of the No Observed Effect Concentration (NOEC) and Lowest Observed Effect Concentration (LOEC).

## ATTACHMENT A

### LITERATURE EVALUATION CRITERIA

#### **No. 1 Testing was Done Under Conditions of High Bioavailability.**

Bioavailability of metals and polar organic compounds is influenced by pH and soil organic matter. The scoring is intended to favor relatively high bioavailability. If the authors do not present the organic matter content, but presented another measure of organic content; total organic carbon, particulate organic carbon, or organic carbon, these measurements are converted to organic matter content by multiplying them by a factor of 1.72.

**Scoring:** Natural soils are scored using one of the three Bioavailability Tables provided below. These tables are the same as those reported in Chapter 2 where very high or high = 2, medium = 1, and low or very low = 0.

**Score =1** for standard artificial soils (i.e., ASTM, ISO, OECD, i.e., 10% OM, 20% Kaolinite, 69% sand, 1% CaCO<sub>3</sub>) with pH of 4.0 to 8.5. All other artificial soils are scored according to the Bioavailability Tables for natural soils.

#### QUANTITATIVE BIOAVAILABILITY FOR CATIONIC METALS IN NATURAL SOILS

	Low OM (< 2%)	Medium OM (2 - 6%)	High OM (> 6 - 10%)
<b>4 &lt; Soil pH ≤ 5.5</b>	2	2	1
<b>5.5 &lt; Soil pH &lt; 7</b>	2	1	0
<b>7 ≤ Soil pH ≤ 8.5</b>	1	0	0



## QUANTITATIVE BIOAVAILABILITY FOR ANIONIC METALS IN NATURAL SOILS

	Low OM (< 2%)	Medium OM (2 - 6%)	High OM (> 6 - 10%)
<b>4 &lt; Soil pH ≤ 5.5</b>	1	0	0
<b>5.5 &lt; Soil pH &lt; 7</b>	2	1	0
<b>7 ≤ Soil pH ≤ 8.5</b>	2	2	1

## QUANTITATIVE BIOAVAILABILITY FOR ORGANIC CHEMICALS IN NATURAL SOILS

Soil Type	Chemical Type	Organic Matter (%)		
		< 2	2 - 6	> 6 - 10
<b>4 &lt; Soil pH ≤ 5.5</b>	Pesticides/PCBS (Log Koc > 3.5)	2	1	0
	Other Organics (Log Koc < 3.5)	2	2	1
<b>5.5 &lt; Soil pH &lt; 7</b>	Pesticides/PCBS (Log Koc > 3.5)	1	0	0
	Other Organics (Log Koc < 3.5)	2	1	0
<b>7 ≤ Soil pH ≤ 8.5</b>	Pesticides/PCBS (Log Koc > 3.5)	0	0	0
	Other Organics (Log Koc < 3.5)	1	1	0

## **No. 2A Experimental Designs for Laboratory Studies are Documented and Appropriate.**

There are two sections (2A-Laboratory or 2B-Field) for this criterion. Apply the criteria in 2A when the paper describes laboratory studies. Use criteria 2B when the paper describes field studies. Experimental design can significantly influence the quality of a study. Higher quality studies will use an experimental design sufficiently robust to allow analysis of the test variables and discriminate non-treatment effects.

### **Scoring:**

**Score = 2** If a standard method or protocol is cited (e.g., US EPA, OECD, ASTM, ISO), or if a standard method is not cited but the study includes a description of the experimental design<sup>A</sup>, the test conditions<sup>B</sup>, and the nature of the test units<sup>C</sup>, as indicated in the superscripts below;

**Score = 1** If an analysis of variance (ANOVA) or factorial design was used and the number of exposure concentrations is 4 or 5 including a control, or if number of replicate test units are 2 (duplicates). If the study has a regression design and the number of exposure concentrations is 4 or 5 including a control, or  $\geq 6$  without replication (i.e., only one test unit per exposure concentration). The reported toxicity estimate (e.g., effect concentration or EC<sub>x</sub>) encompasses the range of responses needed to describe the dose-response, or extrapolation does not exceed 10% of the highest test concentration. Or, if conditions described in superscript A are met but those in either superscript B or C are not met;

**Score = 0** in all other cases.

<sup>A</sup> The number of exposure concentrations must be  $\geq 6$  including a control, the exposure concentrations (nominal or measured), the number of test organisms per test unit (i.e., loading rate), and the time of observations must be reported in the publication. In addition, if an ANOVA or factorial design was used, there must be at least 3 replicate test units per exposure concentration; or if the study used a regression design, there must be at least two replicates and the toxicity estimate must encompass the range of responses needed to describe the dose-response (e.g., interpolation).

<sup>B</sup> Test conditions reported in the publication should include, at a minimum: exposure temperature. If it is a plant study, it must also report photoperiod (or conditions, e.g., natural light June-August), and type (e.g. sunlight) or intensity of light.

<sup>C</sup> Volume or dimensions, and material comprising the test unit, amount/type of soil in each test unit.

## **No. 2B Experimental Designs for Field Studies are Documented and Appropriate.**

### **Scoring:**

**Score = 2** if the study includes a description of the experimental design<sup>A</sup>, the test conditions<sup>B</sup>, and the nature of the test plots<sup>C</sup>, as directed by the superscripts below;

**Score = 1** if the experimental design is an ANOVA design and has #5 exposure concentrations including controls or <3 replicate test units per exposure concentration, or a regression design with <6 treatments, including a control and no replication, or the test conditions and test units, or test plots, are partially described or not reported, or not cited elsewhere;

**Score = 0** in all other cases.

<sup>A</sup> If experimental plots are used, the study should report the number of exposure concentrations, the number of replicate plots per exposure concentration, the location or method of selecting the sampling locations, and the time of sampling or number of sampling times. If transects were used, the method for selecting the location of the transects, the number of transects, the location or method of selecting the sampling locations along the transects, and the time of sampling, or number of sampling times, should be reported in the publication.

<sup>B</sup> Information on the physico-chemical characteristics of the soil should be reported and, at a minimum, include: soil texture or particle size description (sand, silt, or clay, or some combination thereof), pH, organic matter content.

<sup>C</sup> Size of test plots, or length of transects should be reported or cited elsewhere.

## **No. 3 Concentration of Test Substance in Soil is Reported.**

The concentration of the chemical tested must be reported unambiguously. It is unacceptable, for instance to report application rates (e.g., lbs./acre, to 500 ppm in sludge applied at 10 tons per acre). Studies that only report application rates are not acceptable and should not be used to derive an Eco-SSL. In some cases, greenhouse studies may report soil mass of pots that would make it possible to convert an application rate to a concentration, however, this is rare. Pot volume alone is not be an adequate parameter to calculate concentrations as one would have to approximate the mass. If the concentrations are reported on a wet weight or fresh weight basis it should be recorded in the Comments field, along with any information that would allow conversion to dry weight.

**Scoring:**

**Score = 2** if measured concentrations were reported;

**Score = 1** if toxicity values were based on nominal concentrations and were used in calculating toxicity values;

**Score = 0** in all other cases.

**No. 4 Control Responses are Acceptable.**

Negative controls are a crucial part of toxicity tests in order to distinguish treatment effects from non-treatments effects.

**Scoring:**

**Score = 2** if a standardized procedure was followed and negative control values were within procedural guidelines of the standard procedure cited; or if non-standardized procedure was used and control values were within an acceptable range (e.g., earthworms mortality <10%, plants germination < 20%);

**Score = 1** if results of control were not reported or are ambiguous;

**Score = 0** if control results were not within an acceptable range.

**No. 5 Chronic or Life Cycle Test was Used.**

Chronic toxicity tests, or those assessing long-term adverse sub-lethal impacts on the life-cycle phases of an organism, are considered superior to acute toxicity tests.

**Scoring:**

**Score = 2** if chronic exposures, or life-cycle phase studies were used;

**Score = 1** if acute tests were used;

**Score = 0** if very short term exposures were used (i.e., for physiological measurements).

**No. 6 Chemical Dosing Procedure is Reported and Appropriate for Chemical and Test.**

Chemical dosing procedure may affect the outcome of a test. Chemical dosing procedure will depend on the chemical and the test being done. Typically dosing procedure should include:

- (A) The form or species of the chemical used in the test,
- (B) The carrier or vehicle used to deliver the chemical (e.g., solvent, water, etc.)
- (C) How the carrier was dealt with following dosing (i.e., allowed to volatilize, controls, etc.),
- (D) How soil with chemical was mixed with soil to ensure homogeneity.

**Scoring:**

**Score<sup>A</sup> = 2** if a study references a dosing procedure that includes information for items A-D (above);

**Score<sup>A</sup> = 1** if a study includes information for items A and B, but does not information for items C or D;

**Score = 0** if the study does not specify details of the procedure or they cannot be inferred, or does not meet other scoring criteria.

<sup>A</sup>The evaluator should exercise judgement regarding technical details of all four components (A-D above), and if questionable or unacceptable methods were used, the scores should be lowered by 1 (i.e., the score becomes either 1 or 0) and the rationale for scoring should be stated in the comment section.

**No. 7 Dose-Response Relationship is Reported or can be Established from Reported Data.**

A benchmark concentration is intended to represent the location on the dose-response curve that is the threshold between absence and presence of the effects of concern for a relevant ecological endpoint. Two methodologies can be used to identify this benchmark concentration. The first is a method that generates a no observed effect concentration (NOEC) and a lowest observed effect concentration (LOEC). The NOEC is the concentration that did not cause statistically significant effects when compared to controls. The LOEC is the lowest concentration that resulted in statistically significant effects when compared to controls. The threshold lies somewhere between these two values. The second method involves a statistical model to calculate a dose response curve and estimate an effect concentration for some percentage of the population (ECxx), usually between an EC5 and an EC50. Lethal concentration (LCxx) values will not be used for calculating an Eco-SSL and should not be scored but the information should be recorded on the Critical Notes form. Tests with relatively small upper and lower confidence limits around the NOEC or LOEC and ECx values are preferred. Studies where at least two test concentrations produced adverse effects < 100% are also preferred.

**Scoring:**

**Score = 2** if study reported an EC10, EC15, EC20, EC25, or EC30; or reported a NOEC and LOEC that were within 3x of each other;

**Score = 1** if study reported only an EC50; or the difference between the NOEC or LOEC was  $> 3x$  but  $< 10x$ ;

**Score = 0** if study reported did not report an ECx; or the difference between the NOEC and LOEC  $> 10$ , or only a NOEC *or* LOEC was reported.

#### **No. 8 The Statistical Tests used to Calculate the Benchmark and the Level of Significance were Described.**

When no observed effect concentrations (NOECs) and lowest observed effect concentrations (LOECs) are reported, an ANOVA or other statistical test should have been conducted to determine that the NOEC is the highest test concentration that did not produce a statistically significant effect and the LOEC is the lowest concentration tested that did produce a significant effect when compared to the control. When EC or LC values are reported, the confidence levels around these values should be reported and should be based on a 95% probability level.

##### **Scoring:**

**Score = 2** if the results of the ANOVA or statistical method are presented based on a  $P = 0.05$ ; or the 95% CI of the ECx are presented;

**Score = 1** if the report says that an ANOVA was done but does not state the P level, or the P level was  $> 0.05$ ; or if EC or LC data are presented but not the 95% CIs or used a 90% CI;

**Score = 0** if no NOEC, LOEC, or EC/LCx data are reported, or if they are reported, but there is no description of the methods used to calculate these values.

#### **No. 9 The Origin of the Test Organisms is Described.**

The results of a toxicity test can be influenced by the condition of the test organisms. Test organisms should be healthy and have had no exposure above background to contamination prior to testing.

##### **Scoring:**

**Score = 2** if the source and condition of the test organisms are known and described (for seeds unambiguous information should be provided on species identity), and organisms come from a non-contaminated or commercial source;

**Score = 1** if the organisms are obtained from a non-commercial source that is not adequately described, or sufficient information is not provided about either the seed stock or the commercial source;

**Score = 0** if organisms are from a known contaminated site, or adequate information was not provided about neither the seed stock nor the commercial source.

**Attachment B**  
**Invertebrate and Plant SOP#3**  
**Score Sheet**

(For each criterion, score either 0,1, or 2, with 2 being highest)

Criterion	Title	Study ID					
1	Testing is done under conditions of high bioavailability (See Soil Evaluation Matrix).						
2	Experimental designs are documented and appropriate.						
3	Concentrator in soil of substance of interest is reported						
4	Control Responses are acceptable						
5	Chronic or life cycle test is used.						
6	Chemical dosing procedure was reported and appropriate for chemical and test.						
7	A dose-response relationship is reported or can be estimated from reported data.						
8	The statistical tests used to calculate the benchmark and the levels of significance were described.						
9	The origin of the test organisms were described.						
Total Score (total score equals sum of nine criteria scores)							

**Attachment B**  
**Invertebrate and Plant SOP#3**  
**Score Sheet**

(For each criterion, score either 0,1, or 2, with 2 being highest)

Criterion	#	#	#	#	#	#	#	#	#	#	#	#
1												
2												
3												
4												
5												
6												
7												
8												
9												
Total Score												



**Attachment C**  
**Invertebrate and Plant SOP#3**  
**CRITICAL NOTES**

[illegible]

**Attachment C**  
**Invertebrate and Plant SOP#3**  
**CRITICAL NOTES**

[illegible]



## Appendix 3-2

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# Ecological Soil Screening Level Guidance - Draft

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*Plant and Soil Invertebrate Standard Operating Procedure #4:  
Eco-SSL Derivation, Quality Assurance Review, and Technical  
Write-up*

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*June 27, 2000*

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## **Exhibit 3-4**

### **Plant and Soil Invertebrate Standard Operating Procedure (SOP) #4:**

### **Eco-SSL Derivation, Quality Assurance Review, And Technical Write-up**

**for**

### **Ecological Soil Screening Levels (Eco-SSLs)**

June 27, 2000



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## 1.0 INTRODUCTION

Eco-SSL values are calculated using existing information extracted from available literature. This involves searching literature for published papers and determining the acceptability of retrieved papers for inclusion in the Eco-SSL derivation process (SOP# 1). The papers are reviewed and individual studies are coded for the Ecotox Database (SOP# 2). The acceptable studies are then evaluated and scored for the Eco-SSL process (SOP# 3).

This SOP outlines the process for deriving an Eco-SSLs from the set of information and data captured during the evaluation and scoring process (SOP# 3). All studies that are evaluated using the process in SOP# 3 are assigned an evaluation score, a bioavailability score, and a preference level (A-D). As part of SOP# 3, a preferred toxicity value is also identified for each study.

## 2.0 ECO-SSL DERIVATION

The first step in deriving an Eco-SSL is to sort the studies by their literature evaluation score. Studies with a total evaluation score  $\leq 10$  (out of 18 possible points) are removed from further consideration for deriving an Eco-SSL. Studies that receive an evaluation score  $> 10$  are then ranked by preference level. The Eco-SSL is calculated as the geometric mean of the preferred toxicity values at the highest Preference Level for which sufficient data exists ( $\geq 3$  data points). If there are less than three data points, an Eco-SSL will not be calculated.

Once a draft Eco-SSL has been derived the data set is reviewed for quality assurance by a panel of experts. The reviewers verify that all of the acceptable studies were correctly evaluated and scored. Once the panel has validated the data a technical write-up for the Eco-SSL was prepared.

## 3.0 ECO-SSL CALCULATION

An Eco-SSL is calculated from the highest preference level for which there are three or more values, including all values at higher preference levels. For example, if there are two toxicity values assigned an "A" preference level, but there are four level "B" data point then an Eco-SSL is calculated at the B preference level from both the A and the B toxicity values ( $N = 6$ ). The preferred toxicity values (where  $N \geq 3$ ) are used to calculate the geometric mean (GM) at the highest preference level:

$$GM = \exp(\text{average}(\ln Y_1, Y_2, Y_3 \dots Y_n))$$

The GM of the qualifying toxicity values is the Eco-SSL. By this process the Eco-SSL is derived from the highest quality data available.

In cases where, D Level data are used to derive the Eco-SSL the GM was adjusted by the following appropriate application factor:

- If the  $EC_{50} > MATC$  then the values was divided by 5.
- If the  $EC_{50} < MATC$  then the value was divided by 2.
- If there were only  $EC_{50}$  values then the value was divided by 5.

#### **4.0 QUALITY ASSURANCE REVIEW**

All study data that received an evaluation score  $>9$  (SOP# 3) were reviewed by a panel. During the review process all publications that contained qualifying data were checked by at least two individuals, and reported to the panel for final evaluation. The Quality Assurance reviewers completed the following multi-step process:

- The Literature Acceptance Criteria Checklist (SOP# 1) was used to review and insure that all of the Acceptance Criteria were met.
- The evaluation scores were checked to ensure that all studies that scored  $\leq 10$  were removed from the data set, and all data that scored  $>10$  were retained for further evaluation.
- Each study was reviewed to insure that all of the available data were reported on the Critical Notes (SOP# 3).
- Selection of the appropriate toxicity parameter and ecological endpoints were verified (SOP# 3).
- The bioavailability score from the soil matrix was verified (SOP# 3).
- The preferred toxicity value was verified (SOP# 3).
- The Preference Levels (e.g., A, B, C, etc.) of individual toxicity data was checked and verified.
- The summary statistics are checked to insure that all of the preferred toxicity values are included in the calculations, and that the calculations were correct.





## Appendix 3-3

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# Ecological Soil Screening Level Guidance - Draft

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*Completed Literature Evaluation Scoring Sheets for Studies Used  
to Derive Plant and Soil Invertebrate Eco-SSLs*

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*June 27, 2000*

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## Plant Toxicity Data - Arsenic

Ref	IP#	Exp	Test Organism	Soil pH	%OM	Bio-availability Score	ERE	Tox Parameter	Tox Value	Total Evaluation Score	Level	Used for Eco-SSL
Jacobs, 1970	5577	b	<i>Zea mays</i>	5.5	0.7	2	GRO	MATC	40	13	A	Y
Jacobs, 1970	5577	c	<i>Phaseolus vulgaris</i>	5.5	0.7	2	GRO	MATC	40	13	A	Y
Jacobs, 1970	5577	e	<i>Pisium sativum</i>	5.5	0.7	2	GRO	MATC	97	13	A	Y
Jacobs, 1970	5577	a	<i>Solanum tuberosum</i>	5.5	0.7	2	GRO	MATC	135	12	A	Y
Jiang, 1994	4441	a	<i>Lolium perenne</i>	5.6	0.4	2	GRO	MATC	22	13	A	Y
Jiang, 1994	4441	b	<i>Lolium perenne</i>	4.9	3.1	2	GRO	MATC	22	13	A	Y
Jiang, 1994	4441	f	<i>Hordeum vulgare</i>	4.9	3.1	2	GRO	MATC	22	13	A	Y
Jiang, 1994	4441	g	<i>Hordeum vulgare</i>	5.6	0.4	2	GRO	MATC	112	13	A	Y
Jiang, 1994	4441	e	<i>Hordeum vulgare</i>	5.6	0.4	2	GRO	MATC	4	13	A	Y
Jiang, 1994	4441	c	<i>Lolium perenne</i>	5.6	0.4	2	GRO	MATC	22	13	A	N
Jiang, 1994	4441	d	<i>Lolium perenne</i>	4.9	3.1	2	GRO	MATC	22	13	A	N
Jiang, 1994	4441	h	<i>Hordeum vulgare</i>	4.9	3.1	2	GRO	MATC	22	13	A	N

## Invertebrate Toxicity Data - Cadmium

Ref	IP#	Exp	Test Organism	Bio-availability Score	Soil pH	%OM	ERE	Tox Parameter	Tox Value	Total Evaluation Score	Level	Used for Eco-SSL
Crommentuijn, 93	1913		<i>F. Candida</i>	1	6	10	REP	MATC	220	16	B	Y
Sandifer, 97	758		<i>F. Candida</i>	1	6.0	10.0	REP	MATC	447	16	B	Y
Van Gestel, 97	19	a	<i>F. Candida</i>	1	5.6	10.0	POP	EC10	6	16	B	Y
Van Gestel, 97	19	d	<i>F. Candida</i>	1	5.6	10.0	POP	EC10	19	16	B	Y
Kammenga, 94	5515		<i>P. acuminatus</i>	1	5.5	10.0	POP	MATC	57	14	B	Y
Sandifer, 96	4056	c	<i>F. Candida</i>	1	4.5	10.0	REP	MATC	600	14	B	Y
Sandifer, 96	4056	a	<i>F. Candida</i>	1	6.0	10.0	REP	MATC	600	14	B	Y
Sandifer, 96	4056	b	<i>F. Candida</i>	0	5.0	10.0	REP	MATC	600	13	C	N
Van Gestel, 91	6826		<i>F. andrei</i>	1	6.7	10.0	REP	EC50	108	16	D	N
Van Gestel, 97	19	b	<i>F. Candida</i>	1	5.6	10.0	POP	EC50	58	16	D	N
Van Gestel, 97	19	c	<i>F. Candida</i>	1	5.6	10.0	POP	EC50	92	16	D	N
Crommentuijn, 95	5305		<i>F. Candida</i>	1	6.2	10.0	GRO	EC50	123	15	D	N
Spurgeon, 94	4364		<i>E. fetida</i>	1	6.3	10.0	REP	EC50	46	15	D	N
Spurgeon, 95	6822		<i>E. fetida</i>	1	6.1	10.0	GRO	EC50	215	15	D	N
Van Gestel, 93	6828		<i>E. andrei</i>	1	6.0	10.0	REP			15		N
Neuhaues, 86	1707		<i>E. fetida</i>	1	6.0	10.0	MOR			14		N
Van Gestel, 88	7889		<i>E. fetida</i>	2			MOR			14		N
Donkin, 94	7877		<i>C. Elegan</i>	2			MOR			13		N
Fitzpatric, 96	2550		<i>E. fetida</i>	1	6.5	10.0	MOR			13		N
Korthals, 96	4402		<i>Nematode</i>	2	4.1	3.2	REP			13		N
Wohlgemuth, 90	8485	e	<i>F. Candida</i>	2	5.0	3.0	REP			12		N
Honeycutt, 95	2427		<i>E. fetida</i>	1		10.0	MOR			11		N
Neuhaues, 85	6812		<i>E. fetida</i>	1	6.0	10.0	MOR			11		N
Wohlgemuth, 90	8485	a	<i>F. Candida</i>	1	7.5	0.0	REP			11		N
Wohlgemuth, 90	8485	b	<i>F. Candida</i>	1	7.3	0.5	REP			11		N
Wohlgemuth, 90	8485	c	<i>F. Candida</i>	1	7.2	1.0	REP			11		N
Wohlgemuth, 90	8485	d	<i>F. Candida</i>	0	7.0	5.0	REP			11		N
Wohlgemuth, 90	8485	f	<i>F. Candida</i>	0	7.5	3.5	REP			11		N

## Plant Toxicity Data - Cadmium

Ref	IP#	Exp	Test Organism	Soil pH	%OM	Bio-availability Score	ERE	Tox Parameter	Tox Value	Total Evaluation Score	Level	Used for Eco-SSL
Adema (1989)	2125	a	<i>Lactuca sativa</i>	5.1	3.7	2	GRO	MATC	10	16	A	Y
Adema (1989)	2125	b	<i>Lycopersicum esculentum</i>	5.1	3.7	2	GRO	MATC	57	16	A	Y
Adema (1989)	2125	c	<i>Avena sativa</i>	5.1	3.7	2	GRO	MATC	18	16	A	Y
Dixon 1988	7450	b	<i>Querus rubras</i>	6.0	1.5	2	GRO	MATC	14	16	A	Y
Kelly (1979)	4813	a	<i>Pinus strobus</i>	4.8	1.9	2	GRO	MATC	39	12	A	Y
Kelly (1979)	4813	b	<i>Pinus taeda</i>	4.8	1.9	2	GRO	MATC	39	12	A	Y
Kelly (1979)	4813	c	<i>Betula allenghaniensis</i>	4.8	1.9	2	GRO	MATC	39	12	A	Y
Kelly (1979)	4813	d	<i>Prunus virginiana</i>	4.8	1.9	2	GRO	MATC	39	12	A	Y
Kelly (1979)	4813	e	<i>Pinus strobus</i>	4.8	1.9	2	GRO	MATC	39	12	A	Y
Dixon 1988	7450	a	<i>Querus rubras</i>	6.0	1.5	2	GRO	MATC	32	16	A	N
Adema (1989)	2125	d	<i>Lactuca sativa</i>	7.5	1.4	1	GRO	MATC	57	15	B	N
Adema (1989)	2125	e	<i>Lycopersicum esculentum</i>	7.5	1.4	1	GRO	MATC	3	15	B	N
Adema (1989)	2125	f	<i>Avena sativa</i>	7.5	1.4	1	GRO	MATC	18	15	B	N
Gunther (1998)	7099	a		6.1	1.3	2	GRO	EC50	22	12	D	N
Gunther (1998)	7099	a		6.1	1.3	2	GRO	EC50	390	12	D	N
Gunther (1998)	7099	b		6.1	1.3	2	GRO	EC50	2	12	D	N
Gunther (1998)	7099	b		6.1	1.3	2	GRO	EC50	160	12	D	N
Gunther (1998)	7099	b		6.1	1.3	2	GRO	EC50	112	12	D	N
Gunther (1998)	7099	c		6.1	1.3	2	GRO	EC50	79	12	D	N
Zamen 1998	6719	a		6.9	1.0	2	GRO			11		N
Zamen 1998	6719	a		6.9	1.0	2	GRO			11		N
Zamen 1998	6719	a		6.9	1.0	2	GRO			11		N
Zamen 1998	6719	b		6.9	1.0	2	GRO			11		N
Zamen 1998	6719	b		6.9	1.0	2	GRO			11		N
Zamen 1998	6719	b		6.9	1.0	2	GRO			11		N
Zamen 1998	6719	b		6.9	1.0	2	GRO			11		N

## Plant Toxicity Data - Chromium

Ref	IP#	Exp	Test Organism	Bio-availability Score	Soil pH	%OM	Tox Parameter	Tox Value	Total Evaluation Score	ERE	Level	Used for Eco-SSL
Adema, 1989	2125	a	<i>Avena sativa</i>	2	5.1	3.7	EC50	41	13	GRO	D	Y
Adema, 1989	2125	b	<i>Lycopersicon esculentum</i>	2	5.1	3.7	EC50	31	13	GRO	D	Y
Adema, 1989	2125	d	<i>Avena sativa</i>	1	7.5	1.4	EC50	27	13	GRO	D	Y
Adema, 1989	2125	e	<i>Lycopersicon esculentum</i>	1	7.5	1.4	EC50	27	13	GRO	D	Y
Adema, 1989	2125	f	<i>Latuca sativa</i>	1	7.5	1.4	EC50	22	13	GRO	D	Y
Gunther, 1990	7099	a	<i>Avena sativa</i>	2	6.1	1.3	EC50	25	15	GRO	D	Y
Gunther, 1990	7099	b	<i>Brassica rapa</i>	2	6.1	1.3	EC50	8	15	GRO	D	Y
Adema, 1989	2125	c	<i>Latuca sativa</i>	2	5.1	3.7			13	GRO		N
Kadar, 1998	12988	a	unspecified	1	7.0	0.6			11	GRO		N
Kadar, 1998	12988	b	unspecified	1	7.0	0.6			11	GRO		N
Kadar, 1998	12988	c	unspecified	1	7.0	0.6			11	GRO		N
Kadar, 1998	12988	d	unspecified	1	7.0	0.6			11	GRO		N

# Invertebrate Toxicity Data - Copper

Ref	IP#	Exp	Test Organism	Soil pH	%OM	Bio-availability Score	ERE	Tox Parameter	Tox Value	Total Evaluation Score	Level	Used for Eco-SSL
Korthals, 96	7848	a1	nematodes	4.0	3.7	2	POP	MATC	612	14	A	Y
Svendsen, '97	4449		<i>L. rubellus</i>	6	<1	2	GRO	MATC	226	13	A	Y
Korthals, 96	4402		nematodes	4.1	3.2	2	REP	MATC	141	13	A	Y
Svendsen, '97	11490		<i>E. andrei</i>	5.6	<1	2	REP	MATC	113	15	A	Y
Ma, '84	11146	a	<i>L. rubellus</i>	4.8	5.7	2	REP	MATC	84	14	A	Y
Ma, 88	7854	c	<i>L. rubellus</i>	5	5	2	REP	EC10	80	13	A	Y
Scott-Fordsmand, 97	2288		<i>F. fimertaria</i>	5.5	4.0	2	REP	EC10	38	16	A	Y
Ma, 88	7854	b	<i>A. chlorotica</i>	5	5	2	REP	EC10	28	13	A	Y
Ma, 88	7854	a	<i>A. caliginosa</i>	5	5	2	REP	EC10	27	13	A	Y
Kula, '97	11046	d	<i>E. fetida</i>	5.8	4.0	2	REP	MATC	18	11	A	Y
Kula, '97	11046	b	<i>E. andrei</i>	5.8	4.0	2	REP	MATC	6	11	A	Y
Korthals, 96	7848	a2	<i>Acrobeloides sp.</i>	4.0	3.7	2	POP	MATC	612	14	A	N
Korthals, 96	7848	a3	<i>Cervidellus sp.</i>	4.0	3.7	2	POP	MATC	354	14	A	N
Korthals, 96	7848	b1	nematodes	4.7	3.7	2	POP	MATC	612	14	A	N
Korthals, 96	7848	b2	<i>Trichodorus sp.</i>	4.7	3.7	2	POP	MATC	354	14	A	N
Korthals, 96	7848	b3	<i>Basiria sp.</i>	4.7	3.7	2	POP	MATC	612	14	A	N
Korthals, 96	7848	b4	<i>Diptherophora sp.</i>	4.7	3.7	2	POP	MATC	612	14	A	N
Korthals, 96	7848	c1	<i>Trichodorus sp.</i>	5.4	3.7	2	POP	MATC	612	14	A	N
Korthals, 96	7848	c2	<i>Acrobeloides sp.</i>	5.4	3.7	2	POP	MATC	612	14	A	N
Korthals, 96	7848	c3	<i>Acrobeles sp.</i>	5.4	3.7	2	POP	MATC	354	14	A	N
Korthals, 96	7848	c4	<i>Cervidellus sp.</i>	5.4	3.7	2	POP	MATC	354	14	A	N
Bogomolov, 96	4940		<i>A. tuberculata</i>	6.3	5.0	1	GRO	MATC	141	16	B	N
Kammenga, 96	5515		<i>P. acuminatus</i>	6	10	1	POP	MATC	57	13	B	N
Korthals, 96	7848		<i>Acrobeles sp.</i>	6.1	3.7	1	POP	MATC	612	14	B	N
Korthals, 96	7848		<i>Cervidellus sp.</i>	6.1	3.7	1	POP	MATC	612	14	B	N
Kula, '97	11046	a	<i>E. fetida</i>	6.0	10.0	1	REP	MATC	18	11	B	N
Kula, '97	11046	c	<i>E. andrei</i>	6.0	10.0	1	REP	MATC	179	11	B	N
Ma, '84	11146	b	<i>L. rubellus</i>	6.0	5.7	1	REP	MATC	203	14	B	N
Sandifer, 96	4056	a	<i>F. candida</i>	6	10	1	REP	MATC	447	16	B	N
Sandifer, 96	4056	b	<i>F. candida</i>	5	10	1	REP	MATC	447	16	B	N
Sandifer, 96	4056	c	<i>F. candida</i>	4.5	10	1	REP	MATC	1732	16	B	N
Sandifer, 97	758		<i>F. candida</i>	6.0	10.0	1	REP	MATC	600	13	B	N
Postuma, 97	2380	a	<i>Enchytraeus crypticus</i>	5.5	10	1	REP	EC50		16	D	N

## Invertebrate Toxicity Data - Copper

Ref	IP#	Exp	Test Organism	Soil pH	%OM	Bio-availability Score	ERE	Tox Parameter	Tox Value	Total Evaluation Score	Level	Used for Eco-SSL
Postuma, '97	2380	b	<i>Enchytraeus crypticus</i>	5.5	10	1	REP	EC50		16	D	N
Spurgeon, '94	4364		<i>E. fetida</i>	6.3	10	1	REP	EC50		15	D	N
Spurgeon, '95	6822	a	<i>E. fetida</i>	6.1	10.0	1	GRO	EC50		15	D	N
van Gestal, '89	4111		<i>E. andrei</i>	6	10	1	REP	EC50		13	D	N
Donkin, '93	7838	a	<i>C. elegans</i>	6.0	10.0	2	MOR			14		N
Donkin, '93	7838	b	<i>C. elegans</i>	5.1	3.0	2	MOR			13		N
Donkin, '93	7838	c	<i>C. elegans</i>	6.1	3.4	1	MOR			12		N
Donkin, '93	7838	d	<i>C. elegans</i>	6.2	2.2	1	MOR			12		N
Haque, '83	10944		<i>L. terrist</i>	7.0	10.0	1	MOR			13		N
Neuhaues, '85	6812		<i>E. fetida</i>	6.0	10.0	1	MOR			11		N
Neuhaues, '86	17707		<i>E. fetida</i>	6.0	10.0	1	MOR			14		N
van Gestal, '91	6826				10.0					11		N



# Invertebrate Toxicity Data - Zinc

Ref	IP No.	Exp	Test Organism	Soil pH	%OM	Bio-availability Score	ERE	Tox Parameter	Tox Value	Total Evaluation Score	Level	Used for Eco-SSL
Korthals, 1998	13828		Nematode	4.1	4.0	2	REP	MATC	35	13	A	Y
Korthals, 96	4402		Nematode	4.1	3.2	2	POP	MATC	141	13	A	Y
Smit, 97	4434		<i>F. candida</i>	4.5	1.9	2	REP	EC10	116	17	A	Y
Smit, 98	11279		<i>F. candida</i>	4.8	2.4	2	REP	EC10	99	15	A	Y
Smit, 98	6159	b	<i>F. candida</i>	4.7	2.4	2	REP	EC10	159	17	A	Y
Smit, 98	6159	d	<i>F. candida</i>	4.7	2.4	2	REP	EC10	305	17	A	Y
Sandifer, 96	4056	a	<i>F. candida</i>	6.0	10.0	1	REP	MATC	863	14	B	N
Sandifer, 96	4056	b	<i>F. candida</i>	5.0	10.0	1	REP	MATC	548	14	B	N
Sandifer, 96	4056	c	<i>F. candida</i>	4.5	10.0	1	REP	MATC	548	14	B	N
Sandifer, 97	758		<i>F. candida</i>	6.0	10.0	1	REP	MATC	548	15	B	N
Smit, 98	6159	a	<i>F. candida</i>	6.0	10.0	1	REP	EC10	738	17	B	N
Smit, 98	6159	c	<i>F. candida</i>	7.0	2.0	1	REP	EC10	800	17	B	N
Spurgeon, 96	7870		<i>E. fetida</i>	6.0	10.0	1	REP	MATC	466	12	B	N
Spurgeon, 97	4442	a	<i>E. fetida</i>	6.0	10.0	1	REP	MATC	466	13	B	N
Spurgeon, 97	4442	b	<i>E. fetida</i>	6.0	1.0	1	REP	MATC	466	13	B	N
Van Gestel, 93	6828		<i>E. andrie</i>	6.0	10.0	1	REP	MATC	423	12	B	N
Posthuma, 97	2380	a	<i>E. fetida</i>	6.4	10.0	1	REP			13	D	N
Posthuma, 97	2380	b	<i>E. fetida</i>	6.4	10.0	1	REP			13	D	N
Smit, 96	7869	a	<i>F. candida</i>	6.0	3.0	1	REP			15	D	N
Smit, 96	7869	b	<i>F. candida</i>	6.0	3.5	1	REP			15	D	N
Spurgeon, 94	4364		<i>E. fetida</i>	6.3	10.0	1	REP			11	D	N
Spurgeon, 95	6822		<i>E. fetida</i>	6.1	10.0	1	GRO			11	D	N
Spurgeon, 96	4067	a	<i>E. fetida</i>	4.0	5.0	2	REP			16	D	N
Spurgeon, 96	4067	b	<i>E. fetida</i>	5.0	5.0	2	REP			16	D	N
Spurgeon, 96	4067	c	<i>E. fetida</i>	6.0	5.0	1	REP			16	D	N
Spurgeon, 96	4067	d	<i>E. fetida</i>	4.0	10.0	1	REP			16	D	N
Spurgeon, 96	4067	e	<i>E. fetida</i>	5.0	10.0	1	REP			16	D	N
Spurgeon, 96	4067	f	<i>E. fetida</i>	6.0	10.0	0	REP			16	D	N
Spurgeon, 97	4442	c	<i>E. fetida</i>	6.0	1.0	1	REP			13	D	N
Van Gestel, 97	10987		<i>F. candida</i>	6.0	10.0	1	REP			13	D	N
Donkin, 94	7877	a	<i>C. elegans</i>	6.2	1.7	1	MOR			15		N
Donkin, 94	7877	b	<i>C. elegans</i>	5.1	3.0	2	MOR			15		N
Donkin, 94	7877	c	<i>C. elegans</i>	6.1	3.4	1	MOR			15		N

# **Invertebrate Toxicity Data - Zinc**

<b>Ref</b>	<b>IP No.</b>	<b>Exp</b>	<b>Test Organism</b>	<b>Soil pH</b>	<b>%OM</b>	<b>Bio-availability Score</b>	<b>ERE</b>	<b>Tox Parameter</b>	<b>Tox Value</b>	<b>Total Evaluation Score</b>	<b>Level</b>	<b>Used for Eco-SSL</b>
Donkin, 94	7877	d	<i>C. elegans</i>	6.2	2.2	1	MOR			15		N
Neuhaures, 85	6812		<i>E. fetida</i>	6.0	10.0	1	MOR			11		N
Neuhauser, 86'	17707		<i>E. fetida</i>	6.0	10.0	1	MOR			14		N

## Plant Toxicity Data - Zinc

Ref	IP No.	Exp	Test Organism	Soil pH	%OM	Bio-availability Score	Tox Parameter	Tox Value	ERE	Total Evaluation Score	Level	Used for Eco-SSL
Chlopecka, 1996	11789	b	<i>Zea mays</i>	5.4	2.5	2	MATC	87	GRO	14	A	Y
Chlopecka, 1996	11789	c	<i>Hordeum vulgare</i>	5.4	2.5	2	MATC	87	GRO	14	A	Y
Chlopecka, 1996	11789	a	<i>Zea mays</i>	5.4	2.5	2	MATC	299	GRO	15	A	Y
Roszyk, 1988	13624	c	<i>Avena sativa</i>	5.3	1.5	2	MATC	155	GRO	18	A	Y
Roszyk, 1988	13624	d	<i>Avena sativa</i>	5.6	1.3	2	MATC	361	GRO	18	A	Y
Roszyk, 1988	13624	g	<i>Brassica</i>	5.6	1.3	2	MATC	177	GRO	18	A	Y
Roszyk, 1988	13624	l	<i>Brassica</i>	5.3	1.5	2	MATC	155	GRO	18	A	Y
Roszyk, 1988	13624	m	<i>Avena sativa</i>	5.3	1.5	2	MATC	155	GRO	18	A	Y
Roszyk, 1988	13624	p	<i>Avena sativa</i>	4.3	0.5	2	MATC	143	GRO	18	A	Y
Roszyk, 1988	13624	s	<i>Avena sativa</i>	7.0	1.9	2	MATC	335	GRO	18	A	Y
Roszyk, 1988	13624	u	<i>Avena sativa</i>	5.7	0.8	2	MATC	159	GRO	18	A	Y
Roszyk, 1988	13624	y	<i>Avena sativa</i>	5.9	1.3	2	MATC	328	GRO	18	A	Y
Roszyk, 1988	13624	a	<i>Avena sativa</i>	5.9	1.3	2	MATC	169	GRO	18	A	Y
Roszyk, 1988	13624	b	<i>Avena sativa</i>	5.3	1.5	2	MATC	155	GRO	18	A	Y
Roszyk, 1988	13624	e	<i>Avena sativa</i>	5.6	1.3	2	MATC	361	GRO	18	A	Y
Roszyk, 1988	13624	t	<i>Avena sativa</i>	7.0	1.9	2	MATC	162	GRO	18	A	Y
Roszyk, 1988	13624	v	<i>Avena sativa</i>	5.7	0.8	2	MATC	306	GRO	18	A	Y
Roszyk, 1988	13624	w	<i>Avena sativa</i>	5.7	0.8	2	MATC	159	GRO	18	A	Y
Roszyk, 1988	13624	z	<i>Avena sativa</i>	5.9	1.3	2	MATC	169	GRO	18	A	Y
Biro, 1989	12986	c	<i>Medicago sativum</i>	7.0	3.0	1			PHY	11		N
Biro, 1989	12986	e	<i>Medicago sativum</i>	7.0	3.0	1			PHY	11		N
Biro, 1989	12986	g	<i>Medicago sativum</i>	7.0	3.0	1			GRO	11		N
Foder, 1998	12989	a	<i>Triticum</i>	6.3	3.0	1			GRO	14		N
Foder, 1998	12989	b	<i>Triticum</i>	6.3	3.0	1			GRO	14		N
Foder, 1998	12989	c	<i>Triticum</i>	6.3	3.0	1			GRO	14		N
Foder, 1998	12989	d	<i>Triticum</i>	6.3	3.0	1			GRO	14		N
Foder, 1998	12989	e	<i>Triticum</i>	6.3	3.0	1			GRO	14		N
Foder, 1998	12989	f	<i>Triticum</i>	6.3	3.0	1			GRO	14		N
Foder, 1998	12989	g	<i>Zea mays</i>	6.3	3.0	1			GRO	14		N
Foder, 1998	12989	h	<i>Zea mays</i>	6.3	3.0	1			GRO	14		N

## Plant Toxicity Data - Zinc

Ref	IP No.	Exp	Test Organism	Soil pH	%OM	Bio-availability Score	Tox Parameter	Tox Value	ERE	Total Evaluation Score	Level	Used for Eco-SSL
Kadar, 1998	12988	a	<i>Daucus carota</i>	7.0	0.6	1			GRO	15		N
Kadar, 1998	12988	b	<i>Pisum sativum</i>	7.0	0.6	1			GRO	15		N
Kadar, 1998	12988	c	<i>Pisum sativum</i>	7.0	0.6	1			GRO	15		N
Kadar, 1998	12988	d	<i>Pisum sativum</i>	7.0	0.6	1			GRO	15		N
Kadar, 1998	12988	e	<i>Pisum sativum</i>	7.0	0.6	1			GRO	15		N
Kucharski, 1992	13292		<i>Phaseolus vulgaris</i>	7.1	0.3	1			GRO	12		N
Metha, 1988	13724		<i>Brassica</i>	8.5	0.3	1			GRO	11		N
Roszyk, 1988	13624	a	<i>Avena sativa</i>	4.2	0.4	2			GRO	17		N
Roszyk, 1988	13624	f	<i>Avena sativa</i>	5.6	1.3	2			GRO	16		N
Roszyk, 1988	13624	h	<i>Avena sativa</i>	7.0	1.9	2			GRO	16		N
Roszyk, 1988	13624	i	<i>Avena sativa</i>	7.0	1.9	2			GRO	16		N
Roszyk, 1988	13624	j	<i>Avena sativa</i>	4.2	0.4	2			GRO	17		N
Roszyk, 1988	13624	l	<i>Brassica</i>	5.9	1.3	2			GRO	16		N
Roszyk, 1988	13624	n	<i>Brassica</i>	4.2	0.4	2			GRO	17		N
Roszyk, 1988	13624	o	<i>Avena sativa</i>	4.3	0.5	2			GRO	17		N
Roszyk, 1988	13624	q	<i>Avena sativa</i>	4.3	0.5	2			GRO	17		N
Roszyk, 1988	13624	r	<i>Avena sativa</i>	4.3	0.5	2			GRO	17		N
Roszyk, 1988	13624	x	<i>Avena sativa</i>	5.7	0.8	2			GRO	17		N
Roszyk, 1988	13624	zb		5.6	3.0	1			GRO	17		N
Roszyk, 1988	13624	ze		5.7	3.3	1			GRO	17		N
Roszyk, 1988	13624	zf	<i>Avena sativa</i>	7.1	2.1	1			GRO	18		N
Roszyk, 1988	13624	zg	<i>Avena sativa</i>	7.1	2.1	1			GRO	18		N
Roszyk, 1988	13624	zh	<i>Avena sativa</i>	7.1	2.1	1			GRO	18		N
Roszyk, 1988	13624	zi	<i>Avena sativa</i>	5.6	3.0	1			GRO	16		N
Roszyk, 1988	13624	zj	<i>Avena sativa</i>	5.6	3.0	1			GRO	16		N
Roszyk, 1988	13624	zk	<i>Avena sativa</i>	5.6	3.0	1			GRO	16		N
Roszyk, 1988	13624	zl	<i>Avena sativa</i>	5.7	3.3	1			GRO	16		N
Roszyk, 1988	13624	zm	<i>Brassica</i>	7.1	2.1	1	MATC	157	GRO	17		N
Roszyk, 1988	13624	zc	<i>Avena sativa</i>	5.7	3.3	1	MATC	319	GRO	18		
Roszyk, 1988	13624	zd	<i>Avena sativa</i>	5.7	3.3	1	MATC	319	GRO	18		

## Plant Toxicity Data - Zinc

Ref	IP No.	Exp	Test Organism	Soil pH	%OM	Bio-availability Score	Tox Parameter	Tox Value	ERE	Total Evaluation Score	Level	Used for Eco-SSL
Sheppard, 1993	4146	b	<i>Brassica</i>	6.3	<1	2			GRO	11		N
Sheppard, 1993	4146	c	<i>Brassica</i>	6.3	<1	2			GRO	11		N
Sheppard, 1993	4146	d	<i>Brassica</i>	6.3	<1	2			GRO	11		N
Sheppard, 1993	4146	f	<i>Brassica</i>	6.3	<1	2			GRO	11		N
Sheppard, 1993	4146	a	<i>Brassica</i>	6.3	<1	2	MATC	71	GRO	12		N
Sheppard, 1993	4146	g	<i>Lactuca sativa</i>	6.3	<1	2	MATC	173	GRO	12		N
Sheppard, 1993	4146	e	<i>Brassica</i>	6.3	<1	2			GRO	11		N
Sheppard, 1993	4146	h	<i>Brassica</i>	7.9	2.7	0	MATC	775	GRO	11		N
Sheppard, 1993	4146	i	<i>Brassica</i>	7.9	2.7	0	MATC	424	GRO	12		N
Sheppard, 1993	4146	j	<i>Brassica</i>	7.9	2.7	0	MATC	775	GRO	12		N
Sheppard, 1993	4146	k	<i>Brassica</i>	7.9	2.7	0	MATC	424	GRO	12		N
Sheppard, 1993	4146	l	<i>Brassica</i>	7.9	2.7	0	MATC	775	GRO	12		N
Sheppard, 1993	4146	m	<i>Brassica</i>	7.9	2.7	0	MATC	424	GRO	12		N
Singh, 1991	12701		<i>Triticum</i>	8.2	0.1	1			GRO	13		N
Voros, 1998	12985	a		7.5	6.5	0			GRO	12		N
Voros, 1998	12985	b		7.5	6.5	0			GRO	12		N

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## Appendix 4-1

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# Ecological Soil Screening Level Guidance - Draft

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*Exposure Factors and Bioaccumulation Models for Derivation of  
Wildlife Eco-SSL*

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**June 27, 2000**

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# EXPOSURE FACTORS AND BIOACCUMULATION MODELS FOR DERIVATION OF WILDLIFE ECO-SSL

## 1.0 DERIVATION OF PARAMETER DISTRIBUTIONS FOR WILDLIFE ECO-SSLs

### Body Weight

Body weight data for receptor species from various locations in North America were identified in published literature (Table 1). Distributions were assigned to data from each location based upon the nature of the data; for example normal distributions were assumed for data presented as means and standard deviations, triangular distributions were assumed for data presented as means (or medians), minimum and maximum values, and uniform distributions were assumed for data presented only as minimum and maximum values. Standard errors were converted to standard deviations by multiplying by the square-root of the sample size (if reported). Monte Carlo analyses were performed on the average of the body weight data over all data sources. The resulting distribution (Table 2) was used to represent the distribution of body weights for each receptor species.

### Food Ingestion Rates

Food ingestion rates (FIR) for all receptors were estimated using allometric relationships between body weight and field metabolic rates as reported by Nagy et al. (1999). The relationship is described by a power model of the form:

$$\log(\text{FMR}) = a + b \cdot \log(\text{BW})$$

where:

- FMR = field metabolic rate (kJ/d)
- BW = receptor body weight (g)
- $a$  = point estimate of regression intercept
- $b$  = point estimate of regression slope

In an earlier work, Nagy (1987), applied average metabolizable energy efficiency values (kJ/g dry weight) to the FMR values to estimate daily food ingestion rates (FIR g/d dry weight) for birds and mammals. Regression analyses were then performed to determine how food ingestion varied with body weight. Although conversion of FMR to FIR was not performed as part of the Nagy et al. (1999) paper, data are presented to perform the conversion. FIR-based allometric regression models were developed using the FMR, body weight, and average metabolizable energy efficiency values reported in Nagy et al. (1999). These models are presented in Table 3.

In order to reconstruct the variation in the data on which the linear regression model is based (as is needed in Monte Carlo simulation), one needs to apply Nagy's model (or any linear regression model, in general) as follows (Sokal and Rohlf 1981, p. 459):

$$\log(\text{FIR}) = a + b \cdot \log(\text{BW}) + \varepsilon$$

where:

FIR	= food intake rate (g/d dry weight)
BW	= body weight: normal(mean, std.dev.)
<i>a</i>	= point estimate of regression intercept
<i>b</i>	= point estimate of regression slope
$\varepsilon$	= error term: normal(0, $\sigma$ )
$\sigma$	= the variance of log(FIR) around the point log(BW)

The value  $\sigma$  is derived from the regression analyses and is the square-root mean square error (root MSE; Table 3).

Using the models in Table 3 and the information outlined above, Monte Carlo analyses were used to generate FIR distributions for each receptor species (Table 4). The full form of the model used to derive FIR (g/g/d dry weight) was:

$$\text{FIR} = \left[ 10^{[a + b \cdot \log(\text{BW}) + \varepsilon]} \right] / \text{BW}$$

### Soil Ingestion Rates

Distributions for soil ingestion rates for all receptor species were derived based on the model presented in Beyer et al. (1994):

$$x = (b - y + ay) / (ay - c + b)$$

where:

<i>x</i>	= fraction of soil in diet (dry mass)
<i>a</i>	= digestibility of food (dry mass)
<i>b</i>	= concentration of acid-insoluble ash in food (dry mass)
<i>c</i>	= concentration of acid-insoluble ash in soil (dry mass)
<i>y</i>	= concentration of acid-insoluble ash in scat (dry mass)

Values for each parameter for each receptor species are summarized in Table 5. Correlations among parameters in the soil ingestion model are possible. For example, the concentration of acid-insoluble ash in scat is likely to be positively correlated with both ash in soil and ash in food. Similarly, digestibility of food is likely to be inversely related to both ash in food and ash in scat. Potential biases that may result

from correlations of model parameters were investigated by performing Monte Carlo analyses with and without correlations among variable. Specific data for the correlations were lacking. Therefore, correlations were assumed as follows:

assumed correlations	
Pair	r
a and b	-0.8
a and c	0
a and y	-0.6
b and c	0
b and y	0.6
c and y	0.8

Correlations between digestibility of food and ash content of food were presumed to be greater than digestibility and ash in scat. Similarly, ash in soil was presumed to be more highly correlated with ash in scat than ash in food. Digestibility of food and ash in scat, and ash in food and soil were assumed to be unrelated.

Comparison of distributions resulting from Monte Carlo analyses with correlated and uncorrelated variables indicated no significant differences. Consequently, soil ingestion distributions resulting from the uncorrelated Monte Carlo analyses were used (Table 6).

## 2.0 BIOACCUMULATION MODELS

A summary of all bioaccumulation models selected or derived for application in the EcoSSLs are presented in Table 7. Discussion of derivation and selection of these models is presented below.

### Inorganics and Earthworms, Plants, and Small Mammals

Soil-to-biota bioaccumulation models, both as simple BAFs or as regression models, have recently been developed from published data for earthworms, terrestrial plants, and small mammals (e.g., Sample et al. 1999, Sample et al. 1998a, Sample et al. 1998b, and Bechtel-Jacobs 1998). Bioaccumulation models presented in these reports were selected as the primary means for estimation of concentrations of inorganic contaminants in wildlife foods. If a both BAFs and regression models were available for a given contaminant, the regression model was selected for application provided the model was significant (i.e., the slope differed significantly [ $p \leq 0.05$ ] from 0) and the coefficient of determination ( $r^2$ ) was greater than or equal to 0.2. If neither of these criteria were met, the median BAF was used to estimate bioaccumulation (Table 7).

Soil-to-biota bioaccumulation models were available for all inorganics placed on the initial EcoSSL list except for antimony for plants, earthworms, and small mammals, and barium and beryllium for small mammals. Based on limited data presented in Bechtel-Jacobs (1998) and a recently published study (Baroni et al.2000), BAFs and a log-linear regression model were developed for antimony in plants (Table 7, Figure 1).

Diet-to-tissue BAFs from Baes et al. (1984) were used to estimate concentrations of antimony, barium, and beryllium in tissue of prey consumed by vertebrate predators. Because no earthworm bioaccumulation data were located for antimony, a default BAF of 1 was assumed.

## Organics and Earthworms

Concentrations of organic contaminants in earthworms are assumed to be a function of partitioning between of soil water and the earthworm tissues (Connell and Markwell 1990, Sample et al. 1997, Jager 1998):

$$C_{\text{worm}} = K_{\text{BW}} C_{\text{w}}$$

where:

$$\begin{aligned} C_{\text{worm}} &= \text{concentration in worm (mg/kg dry weight)} \\ K_{\text{BW}} &= \text{biota/soil water partitioning coefficient} \\ C_{\text{w}} &= \text{concentration in soil water (mg/L)} \end{aligned}$$

$K_{\text{BW}}$  was estimated by Connell and Markwell (1990) based on data for 32 lipophilic chemicals in earthworms:

$$\log K_{\text{bw}} = \log K_{\text{ow}} - 0.6$$

To reconstruct the variation in the data on which the linear regression model for  $K_{\text{BW}}$  is based, regression analyses were redone using the data presented in Connell and Markwell (1990), resulting in the following:

$$\log K_{\text{bw}} = 1.001 * [\log K_{\text{ow}}] - 0.553 + \epsilon \quad (n=100, r^2=0.83)$$

where:

$$\begin{aligned} \epsilon &= \text{regression error (normal distribution, mean=0, STD}=\sigma) \\ \sigma &= \text{square root mean square error from the regression} = 0.63566 \end{aligned}$$

The conventional formula for estimation of the concentration of a chemical in water ( $C_{\text{w}}$ ) based on concentrations in soil is:

$$C_{\text{w}} = C_{\text{s}} / K_{\text{d}}$$

where:

$$C_{\text{s}} = \text{concentration in soil (mg/kg dry weight)}$$



$K_d$  = soil(or sediment)/water partitioning coefficient

For non-ionic organic compounds,  $K_d$  may be estimated as:

$$K_d = f_{oc} K_{oc}$$

where

$f_{oc}$  = fraction of organic carbon in soil  
 $K_{oc}$  = water/ soil organic carbon partitioning coefficient

Specific values of  $K_{oc}$  may not be available for all possible chemicals. Therefore, a family of models for estimation of  $K_{oc}$  from  $K_{ow}$  for different classes of chemicals was developed based on data presented in Gerstl (1990):

**PCBs:**

$$\log K_{oc} = 0.890 * (\log K_{ow}) - 0.732 + \varepsilon \text{ (root MSE}=0.56569, n=15, r^2=0.70)$$

**Nonpolar PAHs:**

$$\log K_{oc} = 0.890 * (\log K_{ow}) + 0.279 + \varepsilon \text{ (root MSE}=0.32984, n=14, r^2=0.90)$$

**Aromatic Halogenated Hydrocarbons:**

$$\log K_{oc} = 0.974 * (\log K_{ow}) - 0.224 + \varepsilon \text{ (root MSE}=0.34944, n=26, r^2=0.88)$$

**Aromatic Non-halogenated Hydrocarbons:**

$$\log K_{oc} = 0.529 * (\log K_{ow}) + 0.918 + \varepsilon \text{ (root MSE}=0.37489, n=37, r^2=0.66)$$

**Chlorophenols:**

$$\log K_{oc} = 1.076 * (\log K_{ow}) - 0.801 + \varepsilon \text{ (root MSE}=0.23701, n=8, r^2=0.91)$$

**Triazines:**

$$\log K_{oc} = 0.586 * (\log K_{ow}) + 0.826 + \varepsilon \text{ (root MSE}=0.18291, n=12, r^2=0.89)$$

The set of models outlined above for estimating  $K_{BW}$ ,  $K_d$ ,  $K_{oc}$ , and  $C_w$  were combined as follows to produce an overall model for estimation of BAFs for earthworms:

Original model:

$$C_{\text{worm}} = K_{\text{BW}} \times C_{\text{w}}$$

substitute  $C_s/K_d$  for  $C_w$ :

$$C_{\text{worm}} = K_{\text{BW}} \times C_s/K_d$$

multiple both sides of equation by  $1/C_s$ :

$$C_{\text{worm}}/C_s = K_{\text{BW}} / K_d$$

Because the BAF is the ratio between concentrations in biota and that in the media they reside in,  $C_{\text{worm}}/C_s = \text{BAF}$ , and the previous equation is equivalent to:

$$\text{BAF} = K_{\text{BW}} / K_d$$

Substitute for  $K_{\text{BW}}$  and  $K_d$ :

$$\text{BAF} = 10^{(\log K_{\text{OW}} - 0.6)} / [f_{\text{oc}} \times 10^{(0.983 \log K_{\text{OW}} + 0.00028)}]$$

To be conservative,  $f_{\text{oc}}$  for Tier 1 calculations is set to 1% (0.01).

Distributions of earthworm BAFs for organic contaminants were generated based using the model outlined above and parameters summarized in Table 8. Regression errors were all assumed to be normally distributed. Distributions for measured  $K_{\text{OC}}$  values were assigned triangular distributions. Resulting distributions for earthworm BAFs for organic contaminants are presented in Table 9.

## Organics and Plants

Models to estimate chemical-specific soil-to-plant foliage BAFs based on  $K_{\text{OW}}$  have previously been developed and reported in Travis and Arms (1988). As part of the model verification process of undertaken for the EcoSSLs, selected data used by Travis and Arms were chosen for verification. Because the data values could not be verified or were found to be erroneous, all literature cited in Travis and Arms (1988) was acquired, and with additional more recent data, a new model to estimate chemical-specific soil-to-plant foliage BAFs based on  $K_{\text{OW}}$  was developed. This new model is:  $\log_{10} \text{BAF} = 1.31 - 0.385(\log_{10} K_{\text{OW}})$  ( $n=463$ ,  $p<0.0001$ ,  $r^2=0.38$ ) and is presented in Figure 2.

In the process of developing data to derive the  $K_{\text{OW}}$ -based model for plant foliage BAFs, bioaccumulation data for chemicals on the initial EcoSSL list was obtained. These data were used to develop chemical specific BAFs or regression models as appropriate. Newly developed chemical-specific BAFs or regression models are presented in Table 7. Use of the  $K_{\text{OW}}$ -based model for

estimation of plant foliage BAFs was necessary for only for three chemicals, pentachlorophenol, RDX and TNT. Resulting distributions for plant BAFs for these three chemicals are presented in Table 10, with summary values presented in Table 7.

### **Organics and Small Mammals**

Similar to plants, models to estimate chemical-specific diet-to-mammal BAFs based on  $K_{OW}$  have previously been developed and reported in Travis and Arms (1988). Because most of these data values also could not be verified or were found to be erroneous, all literature cited in Travis and Arms (1988) was acquired, and with additional more recent data, a new model to estimate chemical-specific diet-to-mammal BAFs based on  $K_{OW}$  was developed. This new model is:  $\log_{10}BAF=0.338-0.145(\log_{10}K_{OW})$  ( $n=55$ ,  $p=0.38$ ,  $r^2=0.015$ ) and is presented in Figure 3. Results of these analyses indicates that diet-to-mammal BAFs cannot be accurately estimated based on  $K_{OW}$ .

In the process of developing data to derive the  $K_{OW}$ -based model for mammal BAFs, bioaccumulation data for chemicals on the initial EcoSSL list was obtained. These data were used to develop chemical specific BAFs or regression models as appropriate. Newly developed chemical-specific BAFs or regression models are presented in Table 7. In addition, a literature-based model for dietary accumulation of pentachlorophenol by chickens was obtained (Stedman et al. 1980; Table 7). No suitable vertebrate bioaccumulation data has been located thus far for PAHs, RDX or TNT. However, due to the rapid metabolism these compounds experience upon ingestion by birds and mammals, bioaccumulation is expected to be minimal.

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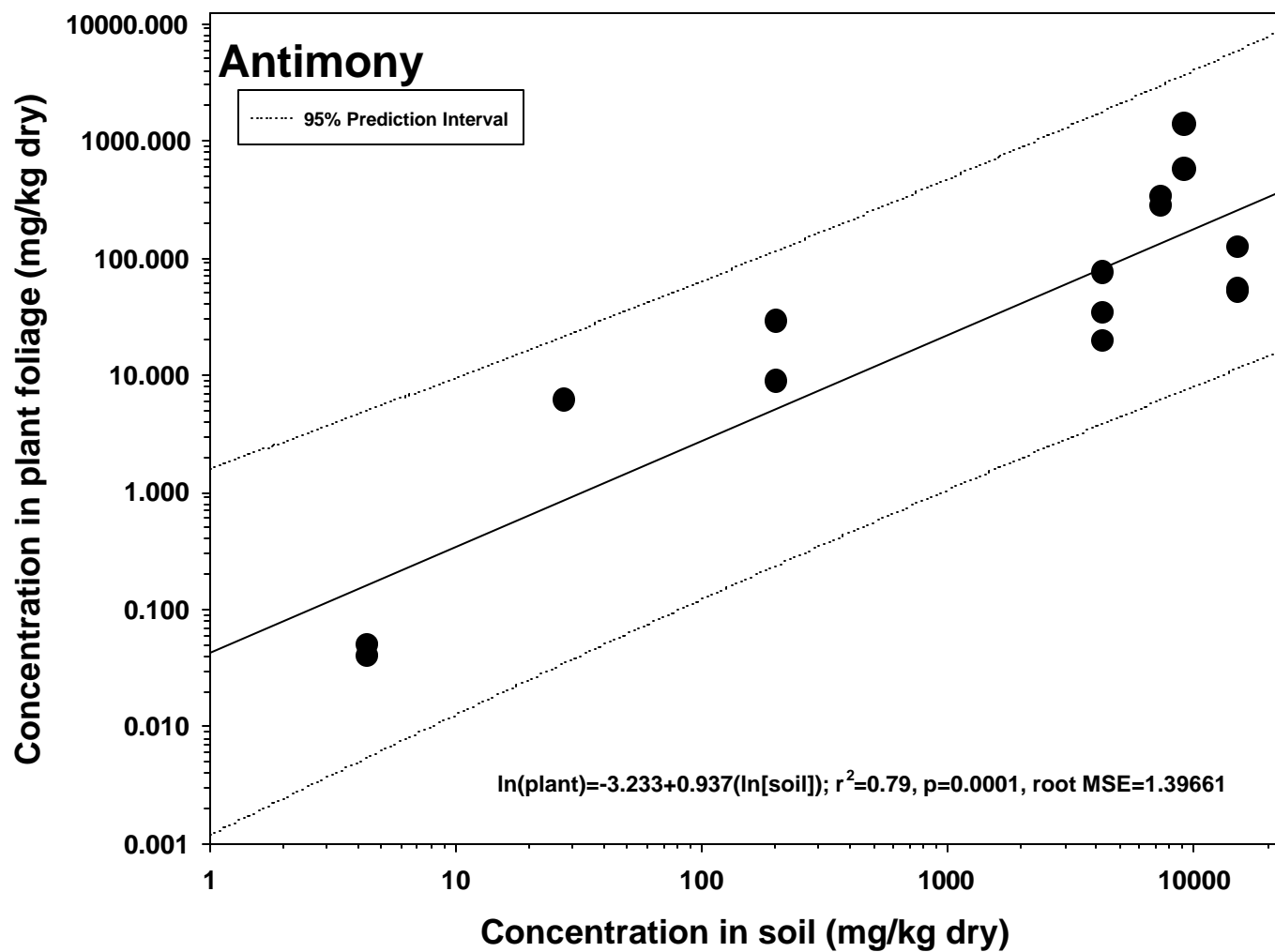


Figure 1. Analysis of bioaccumulation of antimony from soil by plants.

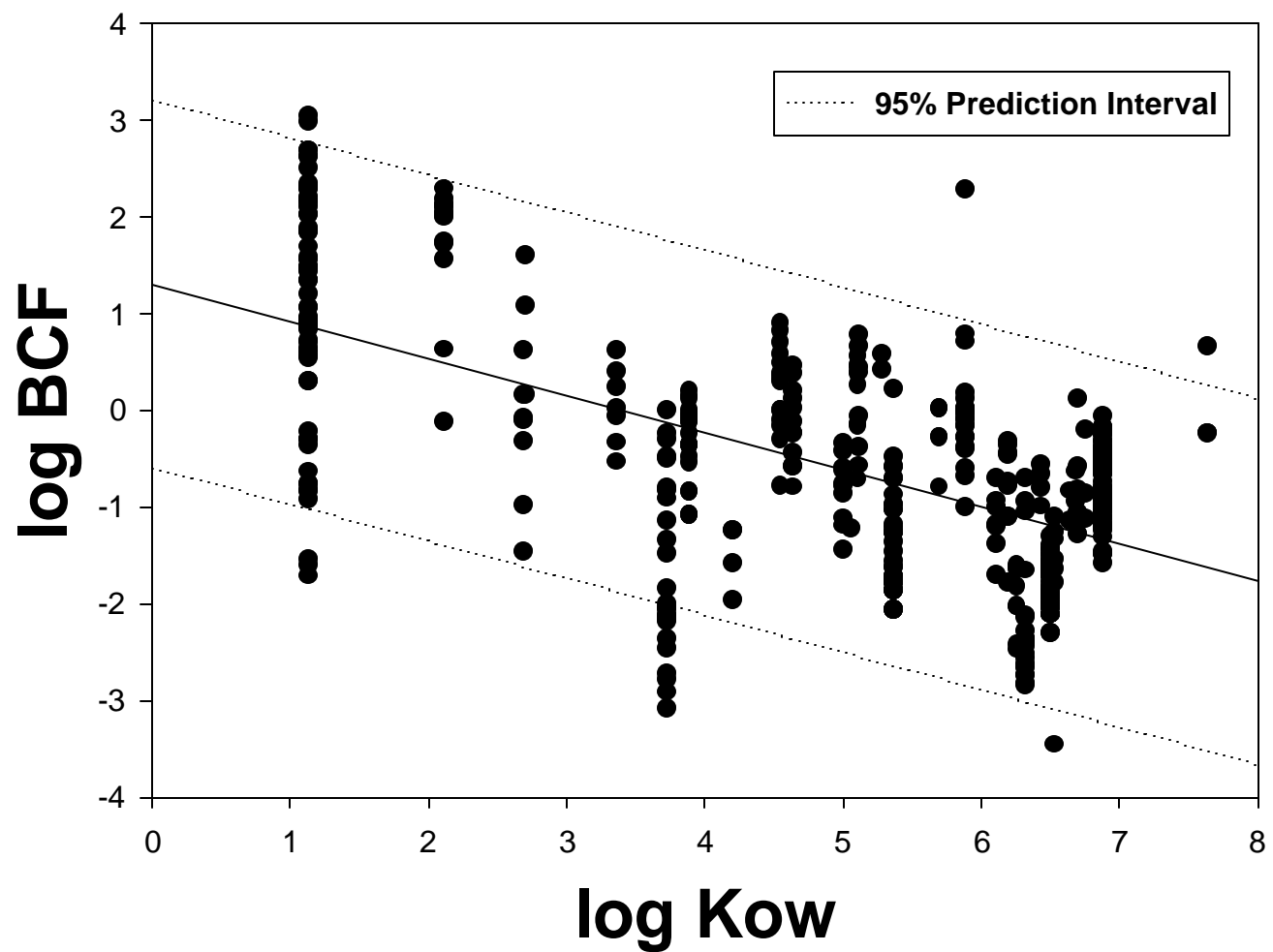
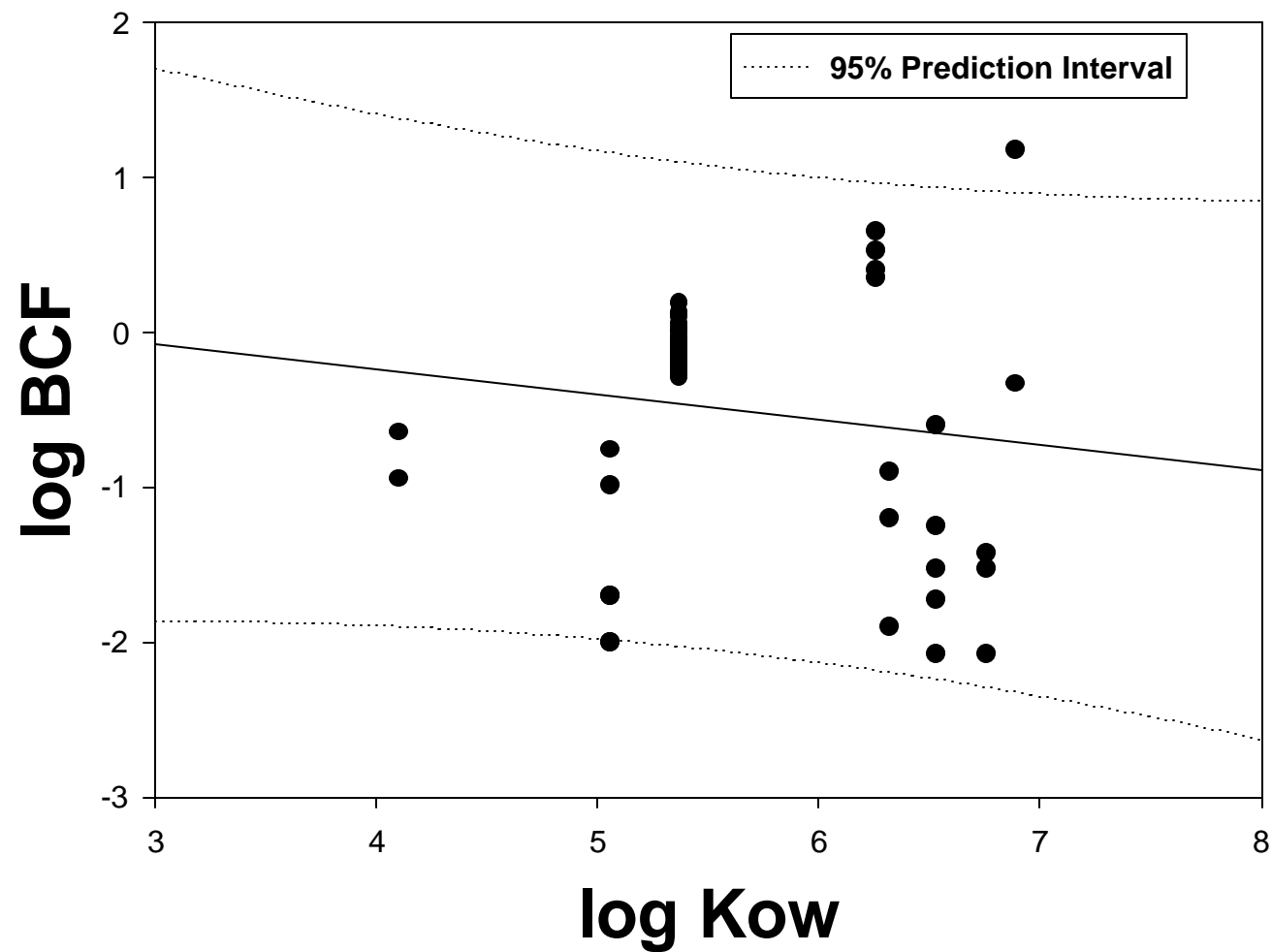


Figure 2. Relationship between  $K_{ow}$  and BCF for organics in plant foliage.





**Figure 3. Relationship between  $K_{ow}$  and BCF for organics in beef tissue.**

**Table 1. Summary of Literature-Derived Body Weight (g) Data for Representative Wildlife Receptor Species.**

Species	n	mean	SD	SE	Min	Max	Sex	Location	Season	Reference	Assumed Distribution
Meadow vole	39	29.4	4.4	0.7			f	Manitoba	.	Innes and Millar 1981	normal
		44.2	6.3				m	.	.	Reich 1981	normal
		44.0	10.3				f	.	.	Reich 1981	normal
		32.5			20.4	48.5	b	Alberta	.	Silva and Downing 1995	triangular
		35.6			29.2	47.2	b	Indiana	.	Silva and Downing 1995	triangular
		38.2			25.1	62.7	m	Indiana	.	Silva and Downing 1995	triangular
		38.8			24.4	63.2	f	Indiana	.	Silva and Downing 1995	triangular
					34.2	46.5	b	New Jersey	.	Silva and Downing 1995	uniform
		36.8			28.0	56.0	f	Virginia	.	Silva and Downing 1995	triangular
		48.8			32.0	71.0	m	Virginia	.	Silva and Downing 1995	triangular
Short-tailed Shrew					25.0	45.0	b	Wyoming	.	Silva and Downing 1995	uniform
	4	16.4	2.5				b	Ohio	.	Barrett and Steuck 1976	normal
	50	19.8	3.1		16.0	28.6	b	Canada	.	vanZyll de Jong 1983	normal
	6	15.9	1.0	0.4			b	Pennsylvania	sept	Merritt 1986	normal
	14	22.2	2.4	0.7			b	Pennsylvania	April	Merritt 1986	normal
		22.0			15.0	29.0	b	Manitoba	.	Silva and Downing 1995	triangular
		17.5			11.0	26.3	m	Indiana	.	Silva and Downing 1995	triangular
		14.1			9.9	19.9	b	Indiana	.	Silva and Downing 1995	triangular
		16.3			11.4	24.8	f	Indiana	.	Silva and Downing 1995	triangular
Long-tailed Weasel					9.0	18.5	b	New Jersey	.	Silva and Downing 1995	uniform
		297.0	36.0				m	Nevada	.	Brown and Lasiewski 1972	normal
		153.0	3.0				f	Nevada	.	Brown and Lasiewski 1972	normal
		200.0	54.0				m	Indiana	.	Mumford and Whitaker 1982	normal
		94.0	10.0				f	Indiana	.	Mumford and Whitaker 1982	normal
					160.0	450.0	m	.	.	Sheffield and Thomas 1997	uniform
					80.0	250.0	f	.	.	Sheffield and Thomas 1997	uniform
					196.0	267.0	m	Virginia	.	Virginia Dept. of Game & Inland Fisheries (1999)	uniform
					101.0	126.0	f	Virginia	.	Virginia Dept. of Game & Inland Fisheries (1999)	uniform
					300.0	500.0	.	Texas	.	Texas Parks & Wildlife (1999)	uniform
Mourning Dove		199.2	35.0				m	Idaho		Johnson 1991	normal
		98.9	14.4				f	Idaho		Johnson 1991	normal
					85.0	250.0	b	Arkansas		Silva and Downing 1995	uniform
		130.0			110.0	170.0	m	.	.	Mirarchi and Baskett 1994	triangular
		116.0			96.0	143.0	m	.	.	Mirarchi and Baskett 1994	triangular
		123.0			100.0	156.0	f	.	.	Mirarchi and Baskett 1994	triangular
Red-tailed Hawk		108.0			86.0	142.0	f	.	.	Mirarchi and Baskett 1994	triangular
	140	123.0	1.9				m	Illinois	.	Dunning 1993	normal
	95	115.0	1.8				f	Illinois	.	Dunning 1993	normal
					690.0	1300.0	m	.	.	Preston and Beane 1993	uniform
American Woodcock					900.0	1460.0	f	.	.	Preston and Beane 1993	uniform
		945.3			698.0	1296.0	m	Wisconsin	.	Preston and Beane 1993	triangular
		1222.0			904.0	1455.0	f	Wisconsin	.	Preston and Beane 1993	triangular
		145.9			127.0	165.0	m	Massachussets	summer	EPA 1993	triangular
		182.9			162.0	216.0	f	Massachussets	summer	EPA 1993	triangular
					116.0	219.0	m	.	.	Keppie and Whiting 1994	uniform
					151.0	279.0	f	.	.	Keppie and Whiting 1994	uniform
		186.6			161.0	214.0	f	Maine	breeding	Keppie and Whiting 1994	triangular
		211.5			163.0	276.0	f	.	nonbreeding	Keppie and Whiting 1994	triangular
		134.9	11.1		116.0	160.0	m	Maine	breeding	Keppie and Whiting 1994	normal
		136.2	4.4				m	New Brunswick	spring	Keppie and Redmond 1985	normal
		135.4	8.1				m	New Brunswick	spring	Keppie and Redmond 1985	normal
		134.1	7.3				m	New Brunswick	spring	Keppie and Redmond 1985	normal
		134.4	8.4				m	New Brunswick	spring	Keppie and Redmond 1985	normal
		133.7	6.7				m	New Brunswick	spring	Keppie and Redmond 1985	normal
		136.1	9.5				m	New Brunswick	spring	Keppie and Redmond 1985	normal

**Table 2. Body Weight (g) Distributions for Representative Wildlife Receptors as Generated from Monte Carlo Analyses of Literature-Derived Data**

	<b>Vole</b>	<b>Shrew</b>	<b>Weasel</b>	<b>Dove</b>	<b>Hawk</b>	<b>Woodcock</b>
Mean	39.86	17.94	202.31	122.04	1076.09	159.01
Std Deviation	1.97	0.80	12.31	3.87	70.34	4.61
Iterations	400.00	200.00	800.00	600.00	400.00	800.00
Minimum	35.38	15.88	168.30	111.56	910.58	144.93
5th Percentile	36.66	16.59	181.78	115.86	965.97	151.14
10th Percentile	37.32	16.90	186.71	116.90	980.76	153.11
15th Percentile	37.80	17.12	189.42	117.87	997.24	154.05
20th Percentile	38.14	17.24	192.06	118.70	1009.46	155.10
25th Percentile	38.39	17.39	193.79	119.42	1027.08	155.91
30th Percentile	38.70	17.49	195.14	120.00	1034.96	156.69
35th Percentile	38.95	17.61	197.24	120.47	1047.50	157.32
40th Percentile	39.31	17.72	198.88	120.97	1057.63	157.74
45th Percentile	39.57	17.82	200.79	121.56	1067.66	158.34
50th Percentile	39.78	17.95	202.18	122.06	1077.80	159.00
55th Percentile	40.06	18.06	204.02	122.62	1086.50	159.77
60th Percentile	40.38	18.19	205.88	123.16	1095.40	160.34
65th Percentile	40.61	18.26	207.40	123.57	1104.02	160.84
70th Percentile	40.87	18.36	209.17	124.08	1112.77	161.50
75th Percentile	41.21	18.44	211.02	124.59	1125.04	162.19
80th Percentile	41.58	18.54	212.95	125.10	1140.95	162.97
85th Percentile	41.91	18.71	215.10	125.92	1151.51	163.73
90th Percentile	42.36	18.88	217.50	126.90	1164.34	164.89
95th Percentile	43.17	19.29	222.44	128.50	1192.10	166.43
Maximum	47.55	20.27	242.50	135.70	1289.53	172.88

**Table 3. Summary of Regression Results Based on Conversion of Nagy et al. (1999) FMR Data to FIR**

<b>Class</b>	<b>Subclass</b>	<b>Order</b>	<b>Trophic Group</b>	<b>n</b>	<b>slope</b>	<b>intercept</b>	<b>root MSE</b>	<b>P</b>	<b>r-square</b>
Birds	.	.	.	95	0.688	-0.2057	0.15909	0.0001	0.94
Mammals	Eutheria	.	.	58	0.744	-0.4889	0.25861	0.0001	0.94
Birds	.	Passeriformes	.	40	0.717	-0.2525	0.11325	0.0001	0.74
Mammals	Eutheria	Rodentia	.	30	0.774	-0.4793	0.2165	0.0001	0.79
Mammals	Eutheria	.	carnivore	12	0.873	-0.9871	0.20937	0.0001	0.93
Mammals	Eutheria	.	herbivore	15	0.579	0.0752	0.28089	0.0001	0.87
Mammals	Eutheria	.	insectivore	10	0.640	-0.5102	0.21193	0.0001	0.89
Mammals	Eutheria	.	omnivore	14	0.696	-0.4007	0.16075	0.0001	0.79
Birds	.	.	carnivore	38	0.664	-0.0758	0.14499	0.0001	0.92
Birds	.	.	granivore	3	0.679	-0.4153	0.31517	0.0001	0.91
Birds	.	.	insectivore	26	0.705	-0.2681	0.1112	0.0001	0.75
Birds	.	.	omnivore	18	0.627	-0.1743	0.17576	0.0001	0.91

model:  $\log_{10}(\text{FIR}) = \text{intercept} + \text{slope} * (\log_{10}[\text{BW}]) + \text{root MSE}$

**Table 4. Food Ingestion Rate Distributions Generated by Monte Carlo Simulation of Allometric Model Derived from Nagy et al. (1999).**

	<b>Vole<sup>1</sup></b>	<b>Shrew<sup>2</sup></b>	<b>Weasel<sup>3</sup></b>	<b>Dove<sup>4</sup></b>	<b>Hawk<sup>5</sup></b>	<b>Woodcock<sup>6</sup></b>
Mean	0.31	0.12	0.06	0.15	0.08	0.13
Std Deviation	0.24	0.06	0.03	0.06	0.03	0.03
Iterations	1600	1600	1600	1600	1600	1600
Minimum	0.04	0.02	0.01	0.05	0.03	0.05
5th Percentile	0.09	0.05	0.02	0.07	0.05	0.08
10th Percentile	0.11	0.06	0.03	0.09	0.05	0.09
15th Percentile	0.12	0.07	0.03	0.09	0.06	0.09
20th Percentile	0.14	0.07	0.03	0.10	0.06	0.10
25th Percentile	0.16	0.08	0.04	0.11	0.06	0.10
30th Percentile	0.18	0.08	0.04	0.12	0.07	0.11
35th Percentile	0.19	0.09	0.04	0.12	0.07	0.11
40th Percentile	0.21	0.09	0.05	0.13	0.07	0.11
45th Percentile	0.23	0.10	0.05	0.13	0.08	0.12
50th Percentile	0.25	0.11	0.05	0.14	0.08	0.12
55th Percentile	0.27	0.11	0.06	0.15	0.08	0.13
60th Percentile	0.29	0.12	0.06	0.15	0.09	0.13
65th Percentile	0.32	0.13	0.06	0.16	0.09	0.13
70th Percentile	0.36	0.14	0.07	0.17	0.10	0.14
75th Percentile	0.40	0.15	0.07	0.18	0.10	0.14
80th Percentile	0.44	0.16	0.08	0.19	0.11	0.15
85th Percentile	0.50	0.18	0.09	0.21	0.11	0.16
90th Percentile	0.58	0.20	0.10	0.23	0.12	0.17
95th Percentile	0.77	0.24	0.11	0.26	0.14	0.18
Maximum	2.93	0.65	0.24	0.52	0.24	0.26

<sup>1</sup> FIR distribution calculated using eutherian herbivore model.

<sup>2</sup> FIR distribution calculated using eutherian insectivore model.

<sup>3</sup> FIR distribution calculated using eutherian carnivore model.

<sup>4</sup> FIR distribution calculated using general avian model.

<sup>5</sup> FIR distribution calculated using avian insectivore model.

<sup>6</sup> FIR distribution calculated using avian carnivore model.

**Table 5. Summary of Parameter Values for Estimation of Soil Ingestion Rates**

<b>Parameter</b>	<b>vole</b>	<b>shrew1</b>	<b>weasel2</b>	<b>dove3</b>	<b>hawk4</b>	<b>woodcock</b>	<b>Assumed Distribution</b>	<b>Notes</b>
b	0 to 0.02	0 to 0.02	0 to 0.02	0 to 0.02	0 to 0.02	0 to 0.02	Uniform	Assumed based on Beyer et al. 1994
a	0.76(0.076)	0.82(0.048)	0.84(0.065)	0.59(0.13)	0.78(0.052)	0.72(0.051)	Normal	Mean (STD) digestibility values presented in Table 4-3 in EPA 1993, except shrew which is from Randolph (1973)
c	0.9 to 1	0.9 to 1	0.9 to 1	0.9 to 1	0.9 to 1	0.9 to 1	Uniform	Assumed based on Beyer et al. 1994
y	0.089 (0.012-0.14)	0.104 (0.067-0.173)	0.14 (0.048-0.25)	0.16 (0.084-0.39)	0.14 (0.048-0.25)	0.22 (0.063-0.40)	Triangular	Mean (range) reported in Beyer et al. 1994 except for shrew.

1 acid insoluble ash in GI tracts from unpubl. data from C. Garten, Oak Ridge National Laboratory.

2 Soil ingestion data for weasel assumed to be comparable to that for red fox reported in Beyer et al. 1994.

3 Soil ingestion data for dove assumed to be comparable to that for wild turkey reported in Beyer et al. 1994.

4 Soil ingestion data for red-tailed hawk assumed to be comparable to that for red fox reported in Beyer et al. 1994.

**Table 6. Soil Ingestion Rate Distributions Generated by Monte Carlo Simulation of Model Derived from Beyer et al. (1994). No Correlations Among Variables Assumed. Total Iterations=3200.**

	<b>Vole</b>	<b>Shrew</b>	<b>Woodcock</b>	<b>Weasel</b>	<b>Dove</b>	<b>Hawk</b>
Mean	0.0138	0.0156	0.0707	0.0165	0.0956	0.0270
Std Deviation	0.0122	0.0112	0.0345	0.0166	0.0505	0.0170
Minimum	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000
5th Percentile	0.0000	0.0000	0.0208	0.0000	0.0279	0.0022
10th Percentile	0.0000	0.0013	0.0289	0.0000	0.0386	0.0063
15th Percentile	0.0009	0.0039	0.0350	0.0000	0.0459	0.0094
20th Percentile	0.0032	0.0058	0.0400	0.0024	0.0523	0.0121
25th Percentile	0.0051	0.0077	0.0452	0.0046	0.0578	0.0147
30th Percentile	0.0069	0.0094	0.0497	0.0068	0.0638	0.0169
35th Percentile	0.0087	0.0108	0.0536	0.0090	0.0695	0.0192
40th Percentile	0.0102	0.0124	0.0581	0.0111	0.0746	0.0212
45th Percentile	0.0116	0.0138	0.0624	0.0131	0.0807	0.0232
50th Percentile	0.0134	0.0153	0.0668	0.0151	0.0877	0.0255
55th Percentile	0.0149	0.0168	0.0715	0.0172	0.0944	0.0279
60th Percentile	0.0165	0.0182	0.0765	0.0194	0.1008	0.0300
65th Percentile	0.0180	0.0198	0.0814	0.0215	0.1089	0.0324
70th Percentile	0.0196	0.0213	0.0871	0.0238	0.1162	0.0348
75th Percentile	0.0217	0.0230	0.0922	0.0266	0.1255	0.0375
80th Percentile	0.0237	0.0253	0.0987	0.0299	0.1354	0.0407
85th Percentile	0.0262	0.0275	0.1079	0.0333	0.1474	0.0445
90th Percentile	0.0298	0.0301	0.1174	0.0390	0.1644	0.0493
95th Percentile	0.0347	0.0344	0.1326	0.0466	0.1918	0.0573
Maximum	0.0595	0.0629	0.2041	0.0761	0.3306	0.0968

Table 7. Summary of Bioaccumulation Models for Food Types Included in the Eco-SSL Wildlife Model. Highlighted Values Represent Recommended Bioaccumulation Data.

Taxa	Analyte	Trophic Group	Transfer type	Summary Statistics for BAFs				Trophic Group	Parameters for log-linear uptake model <sup>1</sup>					Reference
				N	Minimum	Median	Maximum		N	Slope	Intercept	r-square	p (model)	
Plants	Antimony	NA	soil-to-biota	17	0.003	0.037	0.22	NA	17	0.937	-3.233	0.79	0.0001	newly developed for EcoSSLs
Plants	Arsenic	NA	soil-to-biota	122	0.00006	0.03752	9.0741	NA	122	0.564	-1.991	0.15	0.0001	Bechtel-Jacobs 1998
Plants	Barium	NA	soil-to-biota	28	0.036	0.156	0.92	NA	.	.	.	.	.	Bechtel-Jacobs 1998
Plants	Beryllium	NA	soil-to-biota			0.01								Baes et al. 1984
Plants	Cadmium	NA	soil-to-biota	207	0.0087	0.58571	22.8788	NA	207	0.546	-0.475	0.45	0.0001	Bechtel-Jacobs 1998
Plants	Chromium	NA	soil-to-biota	28	0.021	0.041	0.48	NA	.	.	.	.	.	Bechtel-Jacobs 1998
Plants	Cobalt	NA	soil-to-biota	28	0.0019	0.0075	0.045	NA	.	.	.	.	.	Bechtel-Jacobs 1998
Plants	Copper	NA	soil-to-biota	180	0.0011	0.12432	7.4	NA	180	0.394	0.668	0.31	0.0001	Bechtel-Jacobs 1998
Plants	Lead	NA	soil-to-biota	189	0.00011	0.0388	10.6011	NA	189	0.561	-1.328	0.24	0.0001	Bechtel-Jacobs 1998
Plants	Manganese	NA	soil-to-biota	28	0.0199	0.079	0.433	NA	.	.	.	.	.	Bechtel-Jacobs 1998
Plants	Nickel	NA	soil-to-biota	111	0.00217	0.01786	22.2143	NA	111	0.748	-2.223	0.37	0.0001	Bechtel-Jacobs 1998
Plants	Selenium	NA	soil-to-biota	158	0.02	0.67189	77	NA	158	1.104	-0.677	0.63	0.0001	Bechtel-Jacobs 1998
Plants	Silver	NA	soil-to-biota	10	0.0029	0.014	0.04	NA	.	.	.	.	.	Bechtel-Jacobs 1998
Plants	Zinc	NA	soil-to-biota	220	0.00855	0.36616	34.2857	NA	220	0.554	1.575	0.4	0.0001	Bechtel-Jacobs 1998
Plants	Dieldrin	NA	soil-to-biota	41	0.00855	0.024	1.64	NA	41	0.841	-3.271	0.24	0.001	newly developed for EcoSSLs
Plants	DDT	NA	soil-to-biota	7	0.00035	0.028	0.08	NA						newly developed for EcoSSLs
Plants	DDD	NA	soil-to-biota	7	0.00035	0.028	0.08	NA						see footnote 3
Plants	DDE	NA	soil-to-biota	3	0.075	0.136	0.62	NA						newly developed for EcoSSLs
Plants	Pentachlorophenol	NA	soil-to-biota	3600	4.70E-03	9.615071	25277.54	NA						Modeled from Kow, see Table 10
Plants	PAHs													
	Anthracene	NA	soil-to-biota	8	0.16292	1	3.1	NA	8	0.867	0.079	0.62	0.02	newly developed for EcoSSLs
	Benzo(a)anthracene	NA	soil-to-biota	1	0.53704	0.537	0.54							newly developed for EcoSSLs
	Benzo(a)pyrene	NA	soil-to-biota	7	0.01964	0.066	0.2	NA	7	0.635	-2.053	0.61	0.04	newly developed for EcoSSLs
	Benzo(b)fluoranthene	NA	soil-to-biota	6	0.01627	0.173	0.48							newly developed for EcoSSLs
	Benzo(e)pyrene	NA	soil-to-biota	4	0.10169	0.19	0.27							newly developed for EcoSSLs
	Benzo(ghi)perylene	NA	soil-to-biota	7	0.05278	0.131	1.31	NA	7	1.299	-2.565	0.81	0.006	newly developed for EcoSSLs
	Benzo(k)fluoranthene	NA	soil-to-biota	4	0.08	0.255	0.36							newly developed for EcoSSLs
	Chrysene	NA	soil-to-biota	4	0.16216	0.784	1.05							newly developed for EcoSSLs
	Coronene	NA	soil-to-biota	3	0.5787	0.588	4.61							newly developed for EcoSSLs
	Dibenz(ah)anthracene	NA	soil-to-biota	4	0.06977	0.128	0.23							newly developed for EcoSSLs
	Fluoranthene	NA	soil-to-biota	7	0.26838	2.466	6.03							newly developed for EcoSSLs
	Fluorene	NA	soil-to-biota	4	0.01089	0.041	0.06							newly developed for EcoSSLs
	Indeno(123 cd)pyrene	NA	soil-to-biota	2	0.07143	0.11	0.15							newly developed for EcoSSLs
	Naphthlene	NA	soil-to-biota	7	0.29412	1.059	4.19							newly developed for EcoSSLs
	Phenanthrene	NA	soil-to-biota	7	0.69243	3.837	7.92							newly developed for EcoSSLs
	Pyrene	NA	soil-to-biota	7	0.19324	1.852	3.7							newly developed for EcoSSLs
Plants	TNT	NA	soil-to-biota	3600	2.09E-03	5.066329	8714.967	NA						Modeled from Kow, see Table 10
Plants	RDX	NA	soil-to-biota	3600	1.39E-04	0.2418139	553.3746	NA						Modeled from Kow, see Table 10



Table 7. Summary of Bioaccumulation Models for Food Types Included in the Eco-SSL Wildlife Model. Highlighted Values Represent Recommended Bioaccumulation Data.

Taxa	Analyte	Trophic Group	Transfer type	Summary Statistics for BAFs				Trophic Group	Parameters for log-linear uptake model <sup>1</sup>					Reference
				N	Minimum	Median	Maximum		N	Slope	Intercept	r-square	p (model)	
Earthworms	Antimony	NA		.	.	.	.	NA	.	.	.	.	.	
Earthworms	Arsenic	NA	soil-to-biota	53	0.006	0.224	0.925	NA	53	0.706	-1.421	0.26	0.0001	Sample et al. 1999
Earthworms	Barium	NA	soil-to-biota	20	0.005	0.091	0.31	NA	.	.	.	.	.	Sample et al. 1998a
Earthworms	Beryllium	NA	soil-to-biota	12	0	0.045	1.429	NA	.	.	.	.	.	Sample et al. 1998a
Earthworms	Cadmium	NA	soil-to-biota	226	0.253	7.708	190	NA	226	0.795	2.114	0.67	0.0001	Sample et al. 1999
Earthworms	Chromium	NA	soil-to-biota	67	0.021	0.306	11.416	NA	67	-0.067	2.481	0.0026	0.68	Sample et al. 1999
Earthworms	Cobalt	NA	soil-to-biota	17	0.031	0.122	0.321	NA	.	.	.	.	.	Sample et al. 1998a
Earthworms	Copper	NA	soil-to-biota	197	0.002	0.515	5.492	NA	197	0.264	1.675	0.18	0.0001	Sample et al. 1999
Earthworms	Lead	NA	soil-to-biota	245	0	0.266	228.261	NA	245	0.807	-0.218	0.58	0.0001	Sample et al. 1999
Earthworms	Manganese	NA	soil-to-biota	36	0.012	0.054	0.228	NA	36	0.682	-0.809	0.34	0.0002	Sample et al. 1999
Earthworms	Nickel	NA	soil-to-biota	31	0.033	1.059	7.802	NA	31	-0.26	3.677	0.06	0.19	Sample et al. 1999
Earthworms	Selenium	NA	soil-to-biota	14	0.3	0.985	13.733	NA	13	0.733	-0.075	0.43	0.016	Sample et al. 1999
Earthworms	Silver	NA	soil-to-biota	10	0.001	2.045	19.5	NA	.	.	.	.	.	Sample et al. 1998a
Earthworms	Zinc	NA	soil-to-biota	244	0.025	3.201	49.51	NA	244	0.328	4.449	0.45	0.0001	Sample et al. 1999
Earthworms	Dieldrin	NA	soil-to-biota	6300	1.73	267.08	7.70E+05	NA	.	.	.	.	.	Modeled from Kow, see Table 9
Earthworms	DDT	NA	soil-to-biota	6300	0.59	116.61	3.70E+04	NA	.	.	.	.	.	Modeled from Kow, see Table 9
Earthworms	DDD	NA	soil-to-biota	6300	0.27	67.55	4.00E+04	NA	.	.	.	.	.	Modeled from Kow, see Table 9
Earthworms	DDE	NA	soil-to-biota	6300	0.12	73.04	3.80E+04	NA	.	.	.	.	.	Modeled from Kow, see Table 9
Earthworms	Pentachlorophenol	NA	soil-to-biota	6300	0.23	74.68	4.90E+04	NA	.	.	.	.	.	Modeled from Kow, see Table 9
Earthworms	PAHs	NA	soil-to-biota	6300	0.08	50.61	5.30E+04	NA	.	.	.	.	.	Modeled from Kow, see Table 9
	Acenaphthene	NA	soil-to-biota	6300	0.08	38.75	10997.33	NA	.	.	.	.	.	Modeled from Kow, see Table 9
	Anthracene	NA	soil-to-biota	6300	0.14	44.00	6535.99	NA	.	.	.	.	.	Modeled from Kow, see Table 9
	Benzo(a)anthracene	NA	soil-to-biota	6300	0.03	34.45	28284.23	NA	.	.	.	.	.	Modeled from Kow, see Table 9
	Benzo(b)fluoranthene	NA	soil-to-biota	6300	0.10	72.78	52905.02	NA	.	.	.	.	.	Modeled from Kow, see Table 9
	Benzo(k)fluoranthene	NA	soil-to-biota	6300	0.08	71.30	27972.71	NA	.	.	.	.	.	Modeled from Kow, see Table 9
	Benzo(ghi)perylene	NA	soil-to-biota	6300	0.35	81.08	24226.89	NA	.	.	.	.	.	Modeled from Kow, see Table 9
	Benzo(a)pyrene	NA	soil-to-biota	6300	0.14	31.47	11628.95	NA	.	.	.	.	.	Modeled from Kow, see Table 9
	Chrysene	NA	soil-to-biota	6300	0.10	61.78	15876.65	NA	.	.	.	.	.	Modeled from Kow, see Table 9
	Dibenzo(ah)anthracene	NA	soil-to-biota	6300	0.21	78.71	11605.75	NA	.	.	.	.	.	Modeled from Kow, see Table 9
	Naphthalene	NA	soil-to-biota	6300	0.14	50.61	15394.11	NA	.	.	.	.	.	Modeled from Kow, see Table 9
	Phenanthrene	NA	soil-to-biota	6300	0.08	45.49	11607.82	NA	.	.	.	.	.	Modeled from Kow, see Table 9
Earthworms	TNT	NA	soil-to-biota	6300	0.02	19.57	5424	NA	.	.	.	.	.	Modeled from Kow, see Table 9
Earthworms	RDX	NA	soil-to-biota	6300	0.04	9.91	2570	NA	.	.	.	.	.	Modeled from Kow, see Table 9

Table 7. Summary of Bioaccumulation Models for Food Types Included in the Eco-SSL Wildlife Model. Highlighted Values Represent Recommended Bioaccumulation Data.

Taxa	Analyte	Trophic Group	Transfer type	Summary Statistics for BAFs				Trophic Group	Parameters for log-linear uptake model <sup>1</sup>					Reference
				N	Minimum	Median	Maximum		N	Slope	Intercept	r-square	p (model)	
Small Mammals	Antimony		diet-to-biota			0.001								Baes et al. 1984
Small Mammals	Arsenic	General	soil-to-biota	72	0	0.0025	0.071	General	60	0.8188	-4.8471	0.52	0.0001	Sample et al. 1998b
Small Mammals	Barium	.	diet-to-biota	.	.	0.001	.	.	.	.	.	.	.	Baes et al. 1984
Small Mammals	Beryllium	.	diet-to-biota	.	.	0.00015	.	.	.	.	.	.	.	Baes et al. 1984
Small Mammals	Cadmium	Herbivore	soil-to-biota	28	0.0153	0.1258	1	Herbivore	28	0.4723	-1.2571	0.64	0.0001	Sample et al. 1998b
Small Mammals	Chromium	General	soil-to-biota	38	0.0314	0.0846	0.8	General	38	0.7338	-1.4599	0.42	0.0001	Sample et al. 1998b
Small Mammals	Cobalt	General	soil-to-biota	15	0.0101	0.0205	0.18	General	15	1.307	-4.4669	0.41	0.01	Sample et al. 1998b
Small Mammals	Copper	General	soil-to-biota	76	0.0044	0.1963	1.398	General	76	0.1444	2.042	0.26	0.0001	Sample et al. 1998b
Small Mammals	Lead	General	soil-to-biota	138	0.0031	0.1054	2.659	General	138	0.4422	0.0761	0.37	0.0001	Sample et al. 1998b
Small Mammals	Manganese	General	soil-to-biota	12	0.0114	0.0205	0.079	.	.	.	.	.	.	Sample et al. 1998b
Small Mammals	Nickel	General	soil-to-biota	43	0	0.2488	1.143	General	36	0.4658	-0.2462	0.55	0.0001	Sample et al. 1998b
Small Mammals	Selenium	General	soil-to-biota	35	0	0.1619	1.754	General	27	0.3764	-0.4158	0.31	0.0026	Sample et al. 1998b
Small Mammals	Silver	General	soil-to-biota	10	0	0.004	0.81	.	.	.	.	.	.	Sample et al. 1998b
Small Mammals	Zinc	Herbivore	soil-to-biota	30	0.00511	0.504	16.3636	Herbivore	30	0.0706	4.3632	0.31	0.0013	Sample et al. 1998b
Small Mammals	Dieldrin	Beef	diet-to-biota	29	0.35088	0.9091	1.4035							newly developed for EcoSSLs
Small Mammals	DDT	Beef	diet-to-biota	2	0.0188	0.1344	0.25							newly developed for EcoSSLs
Small Mammals	DDD	Beef	diet-to-biota	2	0.0188	0.1344	0.25							see footnote 4
Small Mammals	DDE	Beef	diet-to-biota	3	0.0084	0.0294	0.0372							newly developed for EcoSSLs
Small Mammals	Pentachlorophenol	NA	diet-to-biota	NA	.	.	.	chickens <sup>2</sup>		0.00452	0.198	0.837	.	Stedman et al. 1980
Small Mammals	PAHs													
Small Mammals	TNT													
Small Mammals	RDX													

1 model is of the form:  $\ln(\text{tissue [dry wt.]}) = \text{slope} * (\ln[\text{soil}]) + \text{intercept}$

2 model is for bioaccumulation into breast muscle and is of the form:  $\text{tissue [dry wt.]} = \text{slope} * (\text{diet}) + \text{intercept}$

3 Plant bioaccumulation data were unavailable; bioaccumulation data for DDE is assumed to be representative.

4 Beef bioaccumulation data were unavailable; bioaccumulation data for DDT is assumed to be representative.

**Table 8. Summary of Parameter Values for Estimation of Bioaccumulation of Organic Contaminants from Soil by Earthworms.**

Analyte	log Kow	Source	foc	log Kbw model <sup>1</sup>				Kbw	log Koc model <sup>2</sup>					Koc
				slope	intercept	root MSE	log Kbw		Chemical Class/Source <sup>3</sup>	slope	intercept	root MSE	logKoc	
RDX	0.87	SRC	0.01	1.001334	-0.5528	0.63566	0.32	2.08	Triazine	0.5865	0.8256	0.18291	1.34	21.67
TNT	1.6	SRC	0.01	1.001334	-0.5528	0.63566	1.05	11.20	Aromatic Nonhalogenated Hydrocarbons	0.5289	0.9182	0.37489	1.76	58.14
DDT	6.53	EPA 1996	0.01	1.001334	-0.5528	0.63566	5.99	968079.49	EPA 1996 (n=6)					min=258467 geomean= 677934 max=1741516
DDD	6.1	EPA 1996	0.01	1.001334	-0.5528	0.63566	5.56	359200.89	Aromatic Halogenated Hydrocarbons	0.9739	-0.2238	0.34944	5.72	521182.71
DDE	6.76	EPA 1996	0.01	1.001334	-0.5528	0.63566	6.22	1645196.74	Aromatic Halogenated Hydrocarbons	0.9739	-0.2238	0.34944	6.36	2289623.11
Dieldrin	5.37	EPA 1996	0.01	1.001334	-0.5528	0.63566	4.82	66736.52	EPA 1996 (n=3)					min=23308 geomean= 25546 max=27399
Pentachlorophenol	5.09	EPA 1996	0.01	1.001334	-0.5528	0.63566	4.54	34993.72	Chlorophenols	1.0757	-0.8006	0.23701	4.67	47283.87
Acenaphthene	3.92	EPA 1996	0.01	1.001334	-0.5528	0.63566	3.37	2357.38	Nonpolar PAHs	0.8903	0.2794	0.32984	3.77	5879.98
Anthracene	4.55	EPA 1996	0.01	1.001334	-0.5528	0.63566	4.00	10075.57	EPA 1996 (n=9)					min=14500 geomean= 23493 max=33884
Benzo(a)anthracene	5.7	EPA 1996	0.01	1.001334	-0.5528	0.63566	5.15	142824.86	EPA 1996 (n=4)					min=150000 geomean= 357537 max=840000
Benzo(b)fluoranthene	6.2	EPA 1996	0.01	1.001334	-0.5528	0.63566	5.66	452346.05	Nonpolar PAHs	0.8903	0.2794	0.32984	5.80	629883.16
Benzo(k)fluoranthene	6.2	EPA 1996	0.01	1.001334	-0.5528	0.63566	5.66	452346.05	Nonpolar PAHs	0.8903	0.2794	0.32984	5.80	629883.16
Benzo(ghi)perylene	6.7	EPA 1995	0.01	1.001334	-0.5528	0.63566	6.16	1432642.40	Nonpolar PAHs	0.8903	0.2794	0.32984	6.24	1755537.05
Benzo(a)pyrene	6.11	EPA 1996	0.01	1.001334	-0.5528	0.63566	5.57	367579.04	EPA 1996 (n=3)					min=487947 geomean= 968774 max=2130000
Chrysene	5.7	EPA 1996	0.01	1.001334	-0.5528	0.63566	5.15	142824.86	Nonpolar PAHs	0.8903	0.2794	0.32984	5.35	226000.81
Dibenzo(ah)anthracene	6.69	EPA 1996	0.01	1.001334	-0.5528	0.63566	6.15	1399988.47	EPA 1996 (n=14)					min=565014 geomean= 1789101 max=3059425
Naphthalene	3.36	EPA 1996	0.01	1.001334	-0.5528	0.63566	2.81	648.16	EPA 1996 (n=20)					min=830 geomean= 1191 max=1950
Phenanthrene	4.55	EPA 1995	0.01	1.001334	-0.5528	0.63566	4.00	10075.57	Nonpolar PAHs	0.8903	0.2794	0.32984	4.33	21392.67

w) + error [model from Connell and Markwell 1990 - data reanalyzed]

<sup>1</sup>log Kow) + error [model from Gerstl 1990 - data reanalyzed]

measure Koc available, values were modeled based on chemical class-specific models from Gerstl (1990).

Bs (Aroclor-1260, -1254, -1248, -1242, -1232, -1221, and -1016). ATSDR/TP-88/21

nended Log Kow values. U.S. Environmental Protection Agency, Office of Water, Washington, D.C. 38 pp.

idance: Technical Background Document. EPA/540/R-95/128

ical Properties Database. <http://esc.syrres.com/interkow/PhysProp.htm>

**Table 9. Summary of Distributions for Earthworm BAFs for Organic Contaminants. Total Number of Iterations= 6300.**

	<b>RDX</b>	<b>TNT</b>	<b>DDT</b>	<b>DDD</b>	<b>DDE</b>	<b>Dieldrin</b>	<b>Pentachlorophenol</b>	<b>Acenaphthene</b>	<b>Anthracene</b>	<b>Benzo(a)anthracene</b>	<b>Benzo(b)fluoranthene</b>	<b>Benzo(k)fluoranthene</b>	<b>Benzo(ghi)perylene</b>	<b>Benzo(a)pyrene</b>	<b>Chrysene</b>	<b>Dibenzo(ab)anthracene</b>	<b>Naphthalene</b>	<b>Phenanthrene</b>
Mean	31.29	82.90	368.62	286.60	285.45	751.43	261.18	146.41	124.70	107.23	276.06	263.36	306.18	96.44	240.39	245.30	152.40	182.81
Std Deviation	83.17	263.11	1081.28	1088.32	989.61	1918.34	963.53	451.27	276.17	425.01	969.57	846.82	949.50	265.45	694.91	607.23	413.16	569.09
Minimum	0.04	0.02	0.59	0.27	0.12	1.73	0.23	0.08	0.14	0.03	0.10	0.08	0.35	0.14	0.10	0.21	0.14	0.08
5th Percentile	0.84	1.21	9.66	4.52	4.53	23.21	5.55	2.54	3.56	2.88	5.29	4.79	5.41	2.68	4.05	6.75	4.24	3.20
10th Percentile	1.45	2.18	16.20	7.74	8.42	40.18	10.22	4.52	6.19	5.04	9.34	8.80	9.52	4.62	7.66	11.65	7.36	5.82
15th Percentile	2.08	3.34	23.58	12.16	13.12	57.42	14.94	6.80	9.16	7.28	13.94	13.23	14.10	6.87	11.28	17.12	10.37	8.56
20th Percentile	2.78	4.62	32.13	16.61	18.24	77.70	20.23	9.48	12.29	9.77	18.77	18.36	19.63	9.10	15.45	23.11	14.26	11.67
25th Percentile	3.60	6.12	41.04	22.22	24.06	99.24	25.90	12.68	16.01	12.40	24.52	23.52	26.05	11.57	20.43	29.85	18.13	15.55
30th Percentile	4.43	7.84	52.34	27.86	31.36	123.33	32.69	16.24	20.19	15.79	31.10	29.98	33.49	14.58	26.48	37.46	22.57	19.56
35th Percentile	5.46	9.91	64.64	35.04	39.21	151.62	41.50	20.43	25.11	19.32	38.71	36.95	42.21	17.91	33.49	45.70	28.13	24.29
40th Percentile	6.68	12.56	79.52	43.87	47.83	185.85	51.69	25.37	30.70	23.52	47.98	46.18	52.63	21.48	41.02	55.31	34.57	29.85
45th Percentile	8.25	15.45	97.17	54.23	59.56	223.30	61.68	31.45	36.80	28.32	58.68	57.54	65.53	25.75	50.56	64.94	42.24	37.52
50th Percentile	9.91	19.57	116.61	67.55	73.04	267.08	74.68	38.75	44.00	34.45	72.78	71.30	81.08	31.47	61.78	78.71	50.61	45.49
55th Percentile	11.90	24.38	140.24	82.54	89.29	321.58	89.94	47.09	51.61	40.98	89.08	87.28	98.20	38.43	76.60	96.15	61.39	55.20
60th Percentile	14.43	29.83	170.09	101.70	109.52	382.78	109.86	57.46	63.66	49.66	108.85	108.05	121.22	46.45	94.68	118.83	73.62	68.56
65th Percentile	17.47	37.42	206.56	126.19	139.16	467.10	132.10	72.06	78.92	61.06	135.65	133.17	148.47	55.92	119.33	143.08	90.12	86.40
70th Percentile	21.43	48.18	256.59	163.95	178.46	572.28	163.86	90.93	96.88	76.19	173.09	166.91	183.42	68.85	150.57	179.92	109.69	109.73
75th Percentile	27.40	60.57	318.00	211.62	225.13	708.21	207.60	116.60	120.11	96.83	220.81	209.24	239.61	87.12	190.32	227.49	139.26	142.80
80th Percentile	35.52	78.52	409.19	285.54	294.82	911.78	269.56	153.75	156.06	125.25	287.66	275.45	311.80	111.04	248.16	287.04	175.70	187.71
85th Percentile	48.29	113.33	544.88	401.22	404.06	1183.23	362.30	208.73	208.58	165.69	395.42	381.36	433.30	147.68	332.34	377.79	237.12	257.29
90th Percentile	70.71	167.56	794.48	594.90	580.01	1731.26	529.58	328.54	296.07	236.28	585.06	556.57	665.23	214.66	528.80	556.42	334.25	380.18
95th Percentile	121.94	334.95	1359.72	1039.94	1057.72	2898.34	1004.57	578.37	502.27	412.59	1076.59	1032.45	1204.66	371.52	982.53	934.91	574.76	676.15
Maximum	2570.90	5424.10	36910.07	40189.34	37720.05	76769.38	48667.73	10997.33	6535.99	28284.23	52905.02	27972.71	24226.89	11628.95	15876.65	11605.75	15394.11	11607.82

**Table 10. Summary of Distributions for Plant BAFs for Organic Contaminants. Total Number of Iterations= 3600.**

	<b>RDX</b>	<b>TNT</b>	<b>Pentachlorophenol</b>
Mean	93.84	55.25	2.52
Std Deviation	609.74	292.03	15.29
Minimum	0.005	0.002	0.0001
5th Percentile	0.26	0.14	0.006
10th Percentile	0.53	0.30	0.01
15th Percentile	0.94	0.49	0.02
20th Percentile	1.38	0.77	0.04
25th Percentile	2.14	1.10	0.05
30th Percentile	3.05	1.56	0.07
35th Percentile	4.06	2.11	0.10
40th Percentile	5.40	2.83	0.14
45th Percentile	7.37	3.74	0.18
50th Percentile	9.62	5.07	0.24
55th Percentile	12.60	6.63	0.32
60th Percentile	16.24	9.12	0.43
65th Percentile	22.23	12.38	0.58
70th Percentile	30.42	16.27	0.80
75th Percentile	40.53	22.30	1.11
80th Percentile	57.94	32.27	1.58
85th Percentile	91.74	49.86	2.43
90th Percentile	156.84	85.76	4.10
95th Percentile	352.23	206.14	7.96
Maximum	25277.54	8714.97	553.37



## Appendix 4-2

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# Ecological Soil Screening Level Guidance - Draft

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*Estimation of Exposure Doses and Soil Contaminant  
Concentrations Associated with an  $HQ = 1$*

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*June 27, 2000*

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Draft Calculation of Wildlife Eco-SSLs (23 June 2000)										
Analyte	Species	TRV mg/kg/d	FIR g/g/d	Ps prp	T <sub>ij</sub>	T <sub>vert</sub>	Slope	Intercept	HQ	EcoSSL mg/kg
Antimony	vole	4.4	0.58	0.029			0.937	-3.233	1	117
	shrew	4.4	0.2	0.03	1					21
	weasel	4.4	0.1	0.04	1	0.001				1073
	dove	NA	0.23	0.16						
	woodcock	NA	0.17	0.12						
	hawk	NA	0.12	0.05						
Cobalt	vole	10.4	0.58	0.029	0.0075					491
	shrew	10.4	0.2	0.03	0.122					342
	weasel	10.4	0.1	0.04			1.307	-4.4669	1	1536
	dove	1.3	0.23	0.16	0.0075					34
	woodcock	1.3	0.17	0.12	0.122					32
	hawk	1.3	0.12	0.05			1.307	-4.4669	1	169
Chromium III	vole	24.5	0.58	0.029	0.041					603
	shrew	24.5	0.2	0.03	0.306					365
	weasel	24.5	0.1	0.04			0.7338	-1.4599	1	3043
	dove	1.55	0.23	0.16	0.041					34
	woodcock	1.55	0.17	0.12	0.306					21
	hawk	1.55	0.12	0.05			0.7338	-1.4599	1	83
Chromium VI	vole	22	0.58	0.029	0.041					542
	shrew	22	0.2	0.03	0.306					327
	weasel	22	0.1	0.04			0.7338	-1.4599	1	2687
	dove		0.23	0.16	0.041					
	woodcock		0.17	0.12	0.306					
	hawk		0.12	0.05			0.7338	-1.4599		
Dieldrin	vole	0.8	0.58	0.029			0.841	-3.271	1	20
	shrew	0.8	0.2	0.03	267.1					0.015
	weasel	0.8	0.1	0.04	267.1	0.9091				0.033
	dove	0.48	0.23	0.16			0.841	-3.271	1	10.2
	woodcock	0.48	0.17	0.12	267.1					0.011
	hawk	0.48	0.12	0.05	267.1	0.9091				0.016
RDX	vole	11.55	0.58	0.029	0.242					73
	shrew	11.55	0.2	0.03	9.91					5.8
	weasel	11.55	0.1	0.04	9.91	1				12
	dove	NA	0.23	0.16	0.242					
	woodcock	NA	0.17	0.12	9.91					
	hawk	NA	0.12	0.05	9.91	1				

Calculation of EcoSSLs based on BAFs

$$\text{Eco-SSL} = \text{TRV} / \text{FIR} * (\text{Ps} + \text{T}_{ij})$$

$$\text{Eco-SSL}_{\text{pred}} = \text{TRV} / (\text{FIR} * (\text{Ps} + (\text{T}_{ij} * \text{T}_{\text{vert}})))$$

All Eco-SSLs based on 90th percentiles from FIR and P<sub>s</sub> distributions. BAFs are medians. Bioaccumulation models are mean parameter values.





## Appendix 4-3

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# Ecological Soil Screening Level Guidance - Draft

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*Wildlife TRV Standard Operating Procedure # 2: Literature  
Review, Data Extraction and Coding*

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*June 27, 2000*

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## **Appendix 4-3**

# **Wildlife Toxicity Reference Value Standard Operating Procedure (SOP) #2: Literature Review, Data Extraction and Coding**

**for**

## **Ecological Soil Screening Levels (Eco-SSLs)**

June 27, 2000



**Prepared for USEPA Region 8**

**by**

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999 18th Street, Suite 1450  
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## 1.0 INTRODUCTION

### 1.1 Purpose

The United States Environmental Protection Agency (USEPA) Office of Emergency and Remedial Response (OERR) with a multi-stakeholder workgroup has developed risk-based based soil screening levels (Eco-SSLs). Eco-SSLs are concentrations of contaminants in soils that are protective of ecological receptors that commonly come into contact with soil or ingest biota that live in or on soil. Eco-SSLs are derived separately for four groups of ecological receptors: mammals, birds, plants, and soil invertebrates. As such, these values are presumed to provide adequate protection of terrestrial ecosystems.

The Eco-SSLs should be used in the baseline ERA process to identify the contaminants that need to be evaluated further in the characterization of exposure, effects and risk characterization. The Eco-SSLs should be used during Step 2 of the Superfund ERA process, the screening-level risk calculation. This step normally is completed at a time when limited soil concentration data are available, and other site-specific data (e.g., contaminant bioavailability information, area use factors) are not available. It is expected that the Eco-SSLs will be used to screen the site soil data to identify those contaminants that are not of potential ecological concern and do not need to be considered in the subsequent baseline ERA.

Plant and soil biota Eco-SSLs were developed from available plant, soil invertebrate and microbial toxicity data. The mammal and bird Eco-SSLs are the result of back-calculations from a Hazard Quotient (HQ) of 1.0. The HQ is equal to the dose (associated with the contaminant concentration in soil) divided by a toxicity reference value (TRV). Generic food chain models were used to estimate the relationship between the concentration of the contaminant in soil and the dose for the receptor (mg per kg body weight per day). The TRV represents a numerical estimate of a no adverse level (dose) for the respective contaminant.

The procedure(s) for deriving the oral TRVs needed for calculation of Eco-SSLs for mammals and birds is contained within four standard operating procedures (SOPs):

- |        |   |
|--------|---|
| SOP #1 | Literature Search and Retrieval (Exhibit 4-1) |
| SOP #2 | Literature Review, Data Extraction and Coding |
| SOP #3 | Data Evaluation (Appendix 4-4)                |
| SOP #4 | Derivation of the Oral TRV (Appendix 4-5)     |

This document serves as SOP #2 which is Appendix 4-3 of the draft Eco-SSL guidance document.

The SOP describes the procedures used for review and extraction of data from toxicological studies identified as a result of SOP #1 (Exhibit 4-1). The extracted data are then evaluated (scored) for their usefulness in establishing an oral TRV according to procedures provided in SOP 3 (Appendix 4-4). The extracted and scored data is then used to derive TRVs for mammals and birds, according to the procedures outlined in SOP #4 (Appendix 4-5). This SOP also serves as a user's manual for the web-based data entry system used to guide the data extraction process.

## **1.2 Wildlife TRV Database**

The Wildlife TRV database was created as a tool to facilitate efficient and accurate data extraction from individual reviewed toxicological studies. Importing the data directly into an electronic database facilitates the necessary sorting, searching and presentation of the data for the purposes of TRV derivation. The original database was designed using Microsoft Access and included a series of data entry forms. It was envisioned that each of the parties responsible for data entry would receive a copy of the Access database on a zip disk. After all toxicity studies had been entered and coded, each remote database would then be transferred and merged into the master Access database. Due to changes in the data entry process and the addition of USEPA regional users, the use of the Access-based data entry system was reevaluated. Several issues were identified, including: 1) how to update future changes to the database after the initial distribution, 2) how to effectively merge and incorporate all remote databases into the master database, 3) how to distribute the completed master database to all interested parties after the data entry process has been completed, and 4) how to distribute the database for review by external parties.

A web-based data entry system was proposed to resolve these issues. The web based data entry system allows for remote access from any computer with Internet capabilities. Entry to the site is password-protected and limited to only those individuals responsible for data entry. All information entered is sent directly to a master database (temporarily housed at ISSI), avoiding quality assurance problems associated with merging multiple sources into one database. This system also provides immediate access to entered data. Any changes to the data entry process or scoring is immediately reflected on the website. The website also allows users to view summaries of information entered in the form of reports. A master report containing all toxicity and scoring data will be available as part of the Eco-SSL final guidance document.

The final results of the Eco-SSL coding effort will be transferred to EPA, Duluth for incorporation into the ECOTOX database. The coding guidelines used here for the Wildlife TRV effort follow the same basic structure of that used by EPA, Duluth for TERRETOX. There are, however, some necessary additions and exclusions from the TERRETOX coding system. The TRV database is focused on extracting the no observed adverse effect level (NOAEL) and lowest observed adverse effect level (LOAEL) doses from each of the toxicological studies.

## 2.0 REVIEW OF LITERATURE AND REJECTION CRITERIA

At this point in the Wildlife TRV derivation process, the user has available hard copies of literature identified as a result of SOP #1. Each article identified as a result of the literature search process is assigned a unique reference number with the full citation recorded in a reference management software program (ProCite). The hard copies of the literature are housed at the USEPA Region 8 offices in Denver, Colorado and will ultimately be housed at EPA, Duluth.

The ProCite file contains information on the article title, authors, journal or report title, date, volume, issue, page numbers, abstract, keywords, and article retrieval status. The Record Number provides the link between the data entered on the website and the article information identified in the literature search and recorded in the ProCite file. This number is located in the upper-right corner of the article on a small white label.

Example label:

ISSI	Auth: Smith
ISSI-ID: 45	<b>Cobalt</b>

Each article is reviewed to identify whether the study contains data suitable for the Wildlife TRV effort. Table 1 provides a category listing of the types of studies that are not included in the effort. These categories are referred to as rejection categories or criteria.

Table 1. Literature Rejection Categories	
Categories	Description
ACUTE STUDIES (Acu)	Single oral dose studies.
AIR POLLUTION (Air P)	Studies describing the results for air pollution studies.
ALTERED RECEPTOR (Alt)	Studies that describe the effects of the contaminant on surgically-altered or chemically-modified receptors (e.g., right nephrectomy, left renal artery ligation, hormone implant, etc.).
ANATOMICAL STUDIES (Anat)	Studies of anatomy.
BACTERIA (Bact)	Studies on bacteria.
BIOACCUMULATION SURVEY (Bio Acc)	Studies reporting the measurement of the concentration of the contaminant in tissues.
BIOLOGICAL TOXICANT (BioX)	Studies of biological toxicants, including venoms, fungal toxins, <i>Bacillus thuringiensis</i> , other plant, animal, or microbial extracts or toxins.



Table 1. Literature Rejection Categories	
Categories	Description
BIOMARKER (Biom)	Studies reporting results for a biomarker having no reported association with an adverse effect and an exposure dose (or concentration).
CARCINOGENICITY STUDIES (Carcin)	Studies with carcinogenic endpoints.
CHEMICAL METHODS (Chem Meth)	Studies reporting methods for determination of contaminants, purification of chemicals, etc. Studies describing the preparation and analysis of the contaminant in the tissues of the receptor.
CONFERENCE PROCEEDINGS (CP)	Studies reporting conference and symposium proceedings.
DEAD (Dead)	Studies reporting results for dead organisms.
DISSERTATIONS (Diss)	Dissertations are excluded.
DRUG (Drug)	Studies reporting results for testing of drug and therapeutic effects and side-effects. Therapeutic drugs includes vitamins and minerals.
ECOLOGICAL INTERACTIONS (Ecol)	Studies of ecological interactions.
EFFLUENT (Effl)	Studies reporting effects of effluent, sewage, or polluted runoff.
CHEMICAL FATE/METABOLISM (Fate)	Studies reporting what happens to the contaminant, rather than what happens to the organism. Studies describing the intermediary metabolism of the contaminant (e.g., radioactive tracer studies).
FOOD STUDIES (Food)	Food studies
GENE (Gene)	Genetic/mutagenicity studies
HUMAN HEALTH (HHE)	Human health effects; studies with human subjects or with animal subjects as surrogates for human health risk assessment.
IMMUNOLOGY (IMM)	Studies on the effects of contaminants on immunology.
IN VITRO (In Vit)	In Vitro studies, including exposure of cell cultures and excised tissues. In identification, watch for: In Vitro used for embryo and algae studies (codable); whole organisms exposed and an <u>effect</u> quantified using an In Vitro form (probably codable); and studies which also report results of whole-organism tests for comparison.
LEAD SHOT (Lead shot)	Studies administering lead shot as the exposure form. These studies are labeled separately for possible later retrieval and review.
METHODS (Meth)	Studies reporting method with no usable specific toxicity test results.
MINERAL REQUIREMENTS (Mineral)	Studies examining the minerals required for better production of animals for human consumption.

Table 1. Literature Rejection Categories	
Categories	Description
MIXTURE (Mix)	Studies that report data from studies for combinations of single toxicants are excluded; for example studies of the effects of mixtures of copper and cadmium. Exposure in a field setting from contaminated natural soils or waste application to soil may be coded as Field Survey.
MODELING (Model)	Studies reporting only the results of modeling and no new organism toxicity data are reported.
NO DOSE or CONC (No Dose)	Studies with no usable dose or concentration reported. These are usually identified after examination of full paper.
NO DURATION (No Dur)	Studies with no exposure duration--identified after examination of full paper.
NO EFFECT (No Efect)	Studies with no effect reported for a biological test species.
NO ORAL (No Oral)	Studies using non-oral routes of contaminant administration including interperitoneal injection, other injection, inhalation, and dermal exposures.
NO ORGANISM (No Org)	Studies that do not examine a viable organism present or tested.
NO TOXICANT (No Tox)	No toxicant used. Publications often report responses to changes in water or soil chemistry variables, e.g., pH or temperature. Such publications are not included.
NO DOSE RESPONSE (No Resp)	Toxicant used but no dose response reported. The publication may report genetic changes or effects on media chemistry.
NUTRIENT DEFICIENCY (Nut def)	Studies of the effects of nutrient deficiencies. Effects associated with added nutrients are coded.
OTHER AMBIENT CONDITIONS (OAC)	Other ambient conditions: pH, salinity, DO, UV, radiation, etc.
OIL (Oil)	Oil and petroleum products.
PHYSIOLOGY STUDIES (Phys)	Physiology studies
PRIMATE (Prim)	Primate studies are excluded.
PUBL AS (Publ as)	The author states that the information in this report has been published in another source. Data are recorded from only one source. The second citation is noted as Publ As.
QSAR (QSAR)	Quantitative Structure-Activity Relationships is a form of modeling. Publications are rejected if raw toxicity data are not reported or if the toxicity data reported are a secondary form, ie., citing published data.
REGULATIONS (Reg)	Regulations and related publications
REVIEW (Rev)	Studies in which the data reported in the article are not primary data from research conducted by the author. The publication is a compilation of data published elsewhere. These publications are reviewed manually to identify other relevant literature.
SEDIMENT CONC (Sed)	Studies in which the only exposure concentration/dose reported is for the level of a toxicant in sediment.

<b>Table 1. Literature Rejection Categories</b>	
<b>Categories</b>	<b>Description</b>
SOIL CONC (Soil)	Studies in which the only exposure concentration/dose reported is for the level of a toxicant in soil.
STRESSOR (QAC)	Studies recording the effects of a stressor (e.g., radiation, heat, etc.) and the contaminant.
SURVEY (Surv)	Studies reporting the toxicity of a contaminant in the field over a period of time. Often neither a duration nor an exposure concentration is reported.
REPTILE OR AMPHIBIAN (Herp)	Studies on reptiles and amphibians. Papers identified for possible later review.
UNRELATED (Unrel)	Studies that are unrelated to the contaminants and receptor groups of interest.
WATER QUALITY STUDY (Wqual)	Studies of water quality
YEAST (Yeast)	Studies of yeast

If a reviewed article is rejected, the user records the reason for rejection in the ProCite file and the article is not considered further in the process. The results of the literature review and the application of rejection criteria are described for each contaminant of concern in the technical support documentation of the guidance. SOP #4 (Appendix 4-5) describes the process for deriving the Wildlife TRV and also describes the TRV derivation process (outcome of SOPs #1, 2 and 3) for the 24 Eco-SSL contaminants.

## **3.0 WILDLIFE TRV DATABASE WEBSITE**

### **3.1 Location and Log-On**

To access the Eco-SSL Wildlife TRV Database website from an Explorer or Netscape browser, type <http://www.denver.issiinc.com/trv> in the address bar. The system first prompts the user for a logon identification as a user of the ISSI web site. Enter your username and password as directed.

Next the user log on to the TRV application by clicking the hyperlink word "log" to be prompted for their user name and password. The user name and password (the same as the first log in screen) is entered and "Log On" clicked to continue. It is important that users not give their log on information to others, only authorized individuals are allowed access to the Wildlife TRV website for quality assurance purposes. In addition, only database administrators (ISSI) have authorization to modify and delete entries after initial entry has occurred.

### **3.2 Navigation**

Once the User is logged onto the site, the "Welcome" screen appears which is the home page for the TRV database website. The Welcome screen was designed to recognize authorized users. On the left margin of the web page are the available website links. These links include: Home, Logout, Admin, Contacts, Calendar, Data Entry, and Reports.

#### **Home**

If at any time the User wishes to return to the "Welcome" screen they can click on the Home link.

#### **Logout**

To exit the website, the User clicks on the Logout link.

#### **Admin**

Only database administrators and selected authorized individuals have access to the Admin link.

#### **Contacts**

Click on the Contacts link to view address, phone, and email information for individuals in the Eco-SSL Task Group 1. Also provided at the bottom of the screen is contact information for website technical support. Please e-mail or call technical support there are any difficulties navigating the website, errors, or comments.

## **Calendar**

The Calendar link provides a view of upcoming conference calls, task group meetings, workgroup meetings, and deadlines.

## **Data Entry**

The User clicks on the Data Entry link to begin entering study toxicity information from a selected article or report. Three options are listed for data entry: Complete Entry, Modify Existing Records, and Delete Existing Records. To begin entering data from a selected article or document which has not been entered previously, select Complete Entry. The Modify Existing Records and Delete Existing Records selections can only be accessed by database administrators. Data entry is discussed in more detail in the following sections.

## **Reports**

The User clicks on the Reports link to generate reports of information entered to date. Reports are discussed in more detail in the following sections.

## 4.0 CODING GUIDELINES AND DATA ENTRY

Click on the Data Entry Link located on the left margin of the web page and then select Complete Entry to begin entering information from a selected article or report. Once data entry has begun for a specific article or report, continue to enter information until all endpoints have been scored. This "start-to-finish" process ensures fewer errors due to incomplete entries. There is also a time limit for data entry. If the user has not used the web screens for one hour, then the user is automatically logged out.

There are five main data entry screens used to enter study-specific data. These include: Article Information, Study Information, Exposure Information, Endpoint Information, and Score Information. Figure 1 provides a flowchart for data entry. A navigation bar, which summarizes the specific article, phase, and endpoint which is currently being scored, is provided at the top of each data entry screen to identify the User's location throughout the data entry process.

### 4.1 Article Information

#### **Record Number**

The Record Number is a unique number assigned to the article after the literature search. The Record Number provides the link between the data entered on the website and the article information in the ProCite file. This number is located in the upper-right corner of the article on a small white label. The User enters the number in the numeric field provided for the Record Number (eg.: 45).

Example label:

ISSI	Auth: Smith
ISSI-ID: 45	<b>Cobalt</b>

#### **Contaminant of Concern (COC)**

To ensure quality and consistency, a pull down list is provided for all contaminants which are to be reviewed for the Eco-SSL effort. This list is presented in Table 2. The User selects the contaminant from the pull down list provided. The contaminant form for the contaminant used for testing in the reviewed study is entered at the "Exposure Information" screen. If results for several contaminants of potential concern (COPCs) are available in a single article, separate results are entered for each COPC.

Table 2. Contaminants of Concern			
Contaminant Code	Contaminant Name	Contaminant Code	Contaminant Name
Dld	Dieldrin	2,4 DNT	2,4-Dinitrotoluene
PCB	Total PCBs	TAX	Hexahydro-1-(N)-acetyl-3,5-dinitro-1,3,5-triazine
RDX	Hexahydro-1,3,5-trinitro-1,3,5-	SEX	Octahydro-1-(N)-acetyl-3,5,7-trinitro-1,3,5,7-
TNT	TNT	2,6 DNT	2,6-Dinitrotoluene
DDT	Total DDT - DDT	2 Am DNT	2-Amino-4,6-dinitrotoluene
DDD	Total DDT - DDD	4 Am DNT	4-Amino-2,6-dinitrotoluene
DDE	Total DDT - DDE	TNG	Glycerol trinitrate (Nitroglycerin)
PCP	PCP (Petachlorophenol)	Dmg	3,3'-Dimethylbenzidine
Al	Aluminum	Dma	7,12-Dimethylbenz(a)-anthracene
Ba	Barium	Ace	Acenaphthene or Acenaphthylene
Sb	Antimony	Ani	Aniline
As	Arsenic	Ant	Anthracene
Be	Beryllium	Baa	Benz(a)anthracene
Cd	Cadmium	Bap	Benzo(a)pyrene
Cr	Chromium	Bkf	Benzo(k)fluoranthene
Co	Cobalt	Bghip	Benzo(g,h,i)perylene
Cu	Copper	Bbf	Benzo(b)fluoranthene
Fe	Iron	Chr	Chrysene
Pb	Lead	Dbaha	Dibenz(a,h)anthracene
Mn	Manganese	Dbap	Dibenzo(a,e)pyrene
Ni	Nickel	Dbf	Dibenzofuran
Se	Selenium	Fla	Fluoranthene
Ag	Silver	Fl	Fluorene
V	Vanadium	Ind	Indeno(1,2,3-cd)pyrene
Zn	Zinc	Nap	Naphthalene
HMX	Octahydro-1,3,5,7-tetranitro-	Phe	Phenanthrene
Nitro	Nitrobenzene	Pyr	Pyrene
TNB	1,3,5-Trinitrobenzene		
DNB	1,3-Dinitrobenzene		
Tetryl	Methyl-2,4,6-		

### **Author Key**

The Author Key is a text field designed to provide a citation for the article entered. This citation is used to verify the record number and is incorporated into the navigation bar at the top of each page. Author information is entered in the same way the article would be cited in a document, with the author's last name(s) separated by a comma and the year. If there is one author, the citation appears as "Smith, 1997"; if there are two authors, the citation appears as "Smith and Jones, 1997"; if there are three or

more authors, the citation appears as "Smith et al., 1997". The first or middle name initials are not used in the Author Key.

### **Primary Source**

The toxicity data used for the Wildlife TRVs for Eco-SSLs should be reported from primary sources only. Secondary sources are defined as studies where the data reported is not from research conducted by the author and/or the publication is a compilation of data published elsewhere. These secondary sources are coded as "review" or Rev and are examined (referred to as a manual review) to identify other relevant literature. Toxicological testing results reported in secondary sources are NOT entered. The User selects "Yes" or "No" by checking the appropriate box. If "No" is selected, the information entered to this point is saved and the program exits to the "Data Entry" screen.

### **Results Reported for Exposure to a Single Contaminant**

Studies that report results for simultaneous, multiple contaminant exposure for which it is not possible to segregate results for single contaminant exposure(s) are not reviewed. The User selects "Yes" or "No" by checking the appropriate box. If "No" is selected, the information entered to this point is saved and the program exits to the "Data Entry" screen.

When the "Article Information" screen is completed, the User verifies that all data entered are correct and then clicks on "Next" at the bottom of the screen to continue. The User does **not use the back arrow** to return to a previous data entry screen to correct errors; this results in a deletion of information.

## **4.2 Study Information**

### **Are there multiple phases within this article?**

Multiple study phases are present if the study reports different results for any of the following parameters are different: test organism, test location, exposure type, control type, total number of doses, application frequency, or route of exposure. The User does not code the results for male or female exposure groups as separate phases. The User selects "Yes" or "No" by checking the appropriate box. If "No" is selected, the user should click on "Next" at the bottom of the screen to continue. If "Yes" is selected, the User may enter the results for the first phase as described in the following subsections.

### **How many phases?**

The User enters the total number of phases in the study in the numeric field provided. The User then enters a description of each phase including the differences in parameters in the text box provided.



e.g.: Phase 1 - oral exposure to cadmium chloride in food to rats for 10 weeks  
Phase 2 - oral exposure to cadmium chloride in food to mice for 10 weeks

If multiple Phases of a study report the same NOAEL and LOAEL concentrations (or doses) for the same effect measures and test species, the User may then elect to enter results for only one of the Phases. Typically, the results for the longest exposure duration that report the most conservative results (lowest NOAEL or LOAEL) should be entered. The decisions concerning data entry are recorded in this text box.

When the "Study Information" screen is completed, the User verifies that all data entered are correct and then clicks on "Next" at the bottom of the screen to continue. **The User should NOT** use the back arrow to return to a previous data entry screen to correct errors, as this results in deletion of information. Each time the continue button is used at the end of a screen, the data are recorded in the database.

### **4.3 Exposure Information**

#### **Phase Number**

The phase number is automatically generated by the application and corresponds to the phases briefly described in the "Study Information" section. The User should verify that the phase number is correct. If there are any discrepancies, the User should record the specific information and contact an administrator.

#### **Contaminant Form**

The form of contaminant used in the exposure is recorded by the User in the text box provided. The form can be entered as a name or as a contaminant formula (e.g.: Cadmium Chloride or  $\text{CdCl}_2$ ). If the contaminant form is not provided in the article, then the User enters "NR" for Not Reported.

#### **Administered Amount of a Metal (% Molecular Weight)**

Toxicological studies administer metals using compounds containing various amounts of the metal. Some studies report concentrations (or doses) as units of metal per amount of exposure medium (water or diet) (e.g., mg of Co per kg of diet), while others report concentrations (or doses) based on the compound used (e.g., mg of cobalt chloride per kg of diet). For example, if the administered compound is cadmium chloride, then only 61.32 percent was delivered as cadmium (based on the molecular weight (m.w.) for cadmium chloride ( $\text{CdCl}_2$ ) of 183.32 g/mol, of which 61.32 percent is cadmium). A dose of cadmium chloride of 5 is therefore equal to 3.1 of cadmium ( $5 * 61.32\% = 3.1$ ). Table 3 provides a list of contaminant forms and respective percentages of metal. Enter the percent given in the numeric field provided. If the exposure is reported as pure contaminant, enter the number 100.

Table 3. Percentages of Metal			
Contaminant	Compound	CAS #	% of MW as
Aluminum	Aluminum chloride	7446-70-0	20.23
Aluminum	Aluminum fluoride	7784-18-1	32.13
Aluminum	Aluminum nitrate	13473-90-0	12.67
Aluminum	Aluminum potassium sulfate	10043-67-1	10.45
Aluminum	Aluminum sulfate	10043-01-3	15.77
Aluminum	Aluminum sulfate hydrate	57292-32-7	14.98
Aluminum	<del>Aluminum nitrate nonahydrate</del>	7784-27-2	7.19
Aluminum	Aluminum chloride hexahydrate	7784-13-6	11.18
Aluminum	Aluminum trihydrate	21645-51-2	34.59
Aluminum	Aluminum sulfate octahydrate	7784-31-8	8.10
Aluminum	Aluminum fluoride dihydrate	<del>15098-87-0</del>	19.55
Aluminum	Aluminum sulfate hydrate	16828-11-8	9.08
Antimony	Potassium antimonate	<del>29638-69-5</del>	
Antimony	Antimony potassium tartrate	11071-15-1	39.67
Antimony	Antimony trichloride	10025-91-9	53.38
Antimony	Antimony trifluoride	7783-56-4	68.11
Antimony	Antimony trioxide	1309-64-4	83.53
Antimony	Antimony trisulfide	1345-04-6	71.69
Antimony	L-Antimony potassium tartrate	11071-15-1	39.67
Antimony	Potassium hexahydroantimonate	12208-13-8	46.32
Arsenic	Sodium arsenate (NaAsO <sub>4</sub> )	13464-38-5	36.04
Arsenic	Sodium arsenate (generic form)	7631-89-2	45.71
Barium	Barium carbonate	513-77-9	69.59
Barium	Barium acetate	543-80-6	53.77
Barium	Barium chloride dihydrate	10326-27-9	56.22
Barium	Barium sulfate	7727-43-7	58.84
Barium	Barium nitrate	10022-31-8	52.55
Barium	Barium chloride	10361-37-2	65.95
Barium	Barite (barium sulfate)	13462-86-7	58.84
Barium	Barium sulfide	21109-95-5	81.07
Beryllium	Beryllium chloride	7787-47-5	11.27
Beryllium	Beryllium fluoride	7787-49-7	19.17
Beryllium	Beryllium hydroxide	13327-32-7	20.94
Beryllium	Beryllium nitrate (Be(NO <sub>3</sub> ) <sub>2</sub> ·3H <sub>2</sub> O)	7787-55-5	4.82
Beryllium	Beryllium nitrate (BeN <sub>2</sub> O <sub>6</sub> )	13597-99-4	6.77
Beryllium	Beryllium silicate	15191-85-2	<b>16.37</b>
Beryllium	Beryllium sulfate	13510-49-1	8.58
Beryllium	Beryllium sulfate tetrahydrate	7787-56-6	5.09
Cadmium	Cadmium acetate	543-90-8	48.77
Cadmium	Cadmium bromide	7789-42-6	41.29

Table 3. Percentages of Metal			
Contaminant	Compound	CAS #	% of MW as
Cadmium	Cadmium chloride	10108-64-2	61.32
Cadmium	<del>Cadmium iodide (CdI<sub>2</sub>)</del>	<del>7790-80-9</del>	30.69
Cadmium	Cadmium nitrate	10325-94-7	47.55
Cadmium	Cadmium sulfate	10124-36-4	53.92
Cadmium	Cadmium chloride hydrate	7790-78-5	49.23
Cadmium	Cadmium sulfate 8/3H <sub>2</sub> O	7790-84-3	31.88
Chromium	Chromium	7440-47-3	100.00
Chromium	Chromic acid (+6)	7738-94-5	44.06
Chromium	Sodium chromate (+6)	7775-11-3	32.10
Chromium	Chromium fluoride (+3)	7788-97-8	47.71
Chromium	Chromium chloride	10025-73-7	32.83
Chromium	Chromium potassium sulfate (3+)	10141-00-1	18.36
Chromium	Sodium dichromate (+6)	10588-01-9	39.70
Chromium	Chromic acid (+6)	13530-68-2	
Chromium	Chromium (III) nitrate (3+)	13548-38-4	21.85
Chromium	Chromate (CrO <sub>4</sub> )	11104-59-9	44.83
Chromium	Chromium sulfate pentahydrate (+3)	15244-38-9	26.52
Chromium	Hexavalent chromium	18540-29-9	100.00
Chromium	Chromium nitrate nonahydrate	7789-02-8	13.00
Chromium	Potassium dichromate		26.78
Cobalt	Cobalt acetate	71-48-7	33.29
Cobalt	Cobalt chloride	7646-79-9	45.39
Cobalt	Cobalt nitrate	10141-05-6	32.22
Cobalt	Cobalt sulfate	10124-43-3	38.02
Cobalt	Cobalt(2)formate	544-18-3	39.55
Copper	Copper chloride	1344-67-8	47.27
Copper	Copper (II) sulfate	7758-98-7	39.81
Copper	Copper (I) acetate	598-54-9	51.84
Copper	Copper oxychloride	1332-65-6	59.51
Copper	Copper acetate	4180-12-5	51.84
Copper	Cupric acetate	142-71-2	34.99
Copper	Cupric nitrate	3251-23-8	33.88
Copper	Cupric chloride	7447-39-4	47.27
Copper	Cuprous chloride	7758-89-6	64.19
Copper	Cupric perchlorate hexahydrate	13770-18-8	17.15
Copper	Cupric nitrate hemipentahydrate	19004-19-4	27.32
Copper	Copper chloride dihydrate	10125-13-0	37.28
Iron	Ferric chloride	7705-08-0	34.43
Iron	Ferrous chloride	7758-94-3	44.06
Iron	Iron sulfates	10124-49-9	27.93
Iron	Ferric hydroxide	1309-33-7	52.26

Table 3. Percentages of Metal			
Contaminant	Compound	CAS #	% of MW as
Iron	Ferrous sulfide	1317-37-9	63.53
Iron	Ferrous sulfate	7720-78-7	36.77
Iron	Ferric sulfate	10028-22-5	27.93
Iron	Ferrous hydroxide	18624-44-7	52.26
Iron	Ferric sulfate hydrate	10028-22-5	27.93
Iron	Iron trichloride	7705-08-0	34.43
Iron	Iron (II) dichloride tetrahydrate	13478-10-9	28.09
Lead	Lead acetate	301-04-2	63.70
Lead	Lead chloride	7758-95-4	74.50
Lead	Lead nitrate	10099-74-8	62.56
Lead	Lead sulfate	7446-14-2	68.32
Manganese	Manganese (II) chloride	7773-01-5	43.66
Manganese	Manganese (II) nitrate	10377-66-9	30.70
Manganese	Manganese (II) nitrate hydrate	15710-66-4	27.89
Nickel	Nickel chloride hexahydrate	7791-20-0	24.69
Nickel	Nickelous chloride	7718-54-9	45.29
Nickel	Nickelous nitrate	7718-54-9	32.12
Nickel	Nickel sulfate hexahydrate	10101-97-0	22.33
Nickel	Nickelous acetate tetrahydrate	373-02-4	33.20
Nickel	Nickel (II) chloride hydrate	13478-00-7	20.18
Selenium	Selenium dioxide	7446-08-4	71.16
Selenium	Potassium selenate	7790-59-2	35.71
Selenium	Potassium selenite	10431-47-7	38.49
Selenium	Hydrogen selenide	7783-07-5	97.51
Selenium	Selenous acid	7783-00-8	61.22
Selenium	Sodium selenate	13410-01-0	41.79
Selenium	Sodium selenite	10102-18-8	45.66
Selenium	Sodium selenide	1313-85-5	63.20
Selenium	Selenium sulfide	7488-56-4	55.19
Selenium	Selenocystine	1464-43-3	47.27
Selenium	Selenomethionine	1464-42-2	40.26
Vanadium	Vanadium (III) chloride	7718-98-1	32.38
Vanadium	Vanadyl trichloride	7727-18-6	29.39
Vanadium	Vanadic acid, Ammonium salt	7803-55-6	43.55
Vanadium	Sodium vanadate	13718-26-8	41.78
Vanadium	Vanadic acid, Trisodium salt	13721-39-6	26.70
Zinc	Zinc chloride	7646-85-7	47.98
Zinc	Zinc nitrate	7779-88-6	34.52
Zinc	Zinc sulfate	7733-02-0	40.50
Zinc	Zinc acetate	557-34-6	35.64
Zinc	Zinc peroxide	1314-22-3	67.14

Table 3. Percentages of Metal			
Contaminant	Compound	CAS #	% of MW as
Zinc	Zinc phosphide	1314-84-7	76.00
Zinc	Zinc sulfate heptahydrate	7446-20-0	22.74
Zinc	Zinc bromide	7699-45-8	29.04
Zinc	Zinc iodide	10139-47-6	20.49
Zinc	Zinc nitrate hexahydrate	10196-18-6	21.98
Zinc	Zinc acetate dihydrate	5970-45-6	29.79

### **Species Common Name/Laboratory Strain**

The common name or laboratory strain of the test organism is entered in the text box provided. Common name examples include: mouse, rat, dog, chicken, etc.

### **Class**

The class of the test organism is selected by the User from the pull down list. The list of available selections is provided in Table 4.

### **Order**

The available orders in the pull down list are directly related to the class selected above. The User selects the order of the test organism from the pull down list. The list of available selections is provided in Table 4.

### **Family**

The available families in the pull down list are directly related to the order selected above. The User selects the family of the test organism from the pull down list. The list of available selections is provided in Table 4.

### **Genus and Species**

The Latin name (genus and species) of the test organism is entered in the text box provided. If the genus and species are not specified in the article, enter "NR" for Not Reported.

Table 4. Class, Order and Family for Test Species	
Order	Family
AV -- Aves	
Gaviiformes	Gaviidae (loons)
Podicipediformes	Podicipedidae (grebes)
Procellariiformes	Diomedidae (albatrosses)
	Procellariidae (shearwaters, petrels, fulmars)
	Pelacanoididae (diving petrels)
	Hydrobatidae (storm petrels)
Casuariiformes	Casuariidae (cassowaries)
	Dromaiidae (emus)
Struthioniformes	Struthionidae (ostriches)
Rheiformes	Rheidae (rheas)
Tinamiformes	Tinamidae (tinamous)
Pelecaniformes	Pelecanidae (pelicans)
	Sulidae (gannets, boobies)
	Phaethontidae (tropicbirds)
	Phalacrocoracidae (cormorants)
	Anhingidae (darters)
	Fregatidae (frigatebirds)
Sphenisciformes	Spheniscidae (penguins)
Ciconiiformes	Scopidae (hammerhead)
	Balaenicipitidae (whale-headed stork)
	Ardeidae (herons, bitterns)
	Ciconiidae (storks)
	Threskiornithidae (ibises, etc.)
Anseriformes	Anatidae (waterfowl)
	Anhimidae (screamers)
Falconiformes	Cathartidae (New World vultures)
	Sagitariidae (secretary-bird)
	Pandionidae (osprey)
	Accipitridae (kites, Old World vultures, hawks, eagles)
	Falconidae (falcons, caracaras)
Galliformes	Tetraonidae (grouse)
	Phasianidae (quail, pheasants, partridge)
	Meleagrididae (turkeys)
	Megapodidae (megapodes)
	Cracidae (guans, curassows, chachalacas)
	Numididae (guineafowl)

Table 4. Class, Order and Family for Test Species	
Order	Family
Gruiformes	Gruidae (cranes)
	Aramidae (limpkins)
	Rallidae (rails)
	Mesitornithidae (mesites)
	Turnicidae (buttonquails, hemipodes)
	Perdionomidae (plains wanderer)
	Psophiidae (trumpeters)
	Heliornithidae (finfoots)
	Rhynochetidae (kagu)
	Eurypygidiae (sunbittern)
	Cariamidae (seriemas)
	Otididae (bustards)
Phoenicopteriformes	Phoenicopteridae (flamingos)
Charadriiformes	Haematopodidae (oystercatchers)
	Recurvirostridae (stilts, avocets)
	Charadriidae (plovers, lapwings)
	Scolopacidae (sandpipers, etc.)
	Stercorariidae (jaegers, skuas)
	Laridae (gulls)
	Rynchopidae (skimmers)
	Alcidae (auks)
	Sternidae (terns, noddies)
	Jacaniidae (jacanas)
	Rostratulidae (painted snipe)
	Phalaropodidae (phalaropes)
	Dromadidae (crab plover)
	Burhinidae (stonecurlews)
	Glareolidae (pratincoles, thick-knees)
	Thinocoridae (seed snipe)
	Chionididae (sheathbill)
Columbiformes	Columbidae (pigeons, doves)
	Pteroclididae (sandgrouse)
Pstittaciformes	Psittacidae (parrots, lorries, cockatoos, lovebirds, macaws)
Cuculiformes	Cuculidae (cuckoos, etc.)
	Opisthocomidae (hoatzin)
	Musophagidae (turacos)
Strigiformes	Tytonidae (barn owls)
	Strigidae (typical owls)

Table 4. Class, Order and Family for Test Species	
Order	Family
Caprimulgiformes	Caprimulgidae (nightjars, goatsuckers)
	Podargidae (frogmouths)
	Aegothelidae (owlet-nightjars)
	Nyctibiidae (potoos)
	Steatornithidae (oilbird)
Apodiformes	Apodidae (swifts)
	Trochilidae (hummingbirds)
	Hemiprocidae (crested swifts)
Coliiformes	Coliidae (mousebirds or colis)
Trogoniformes	Trogonidae (trogons)
Coraciiformes	Alcedinidae (kingfishers)
	Todidae (todies)
	Momotidae (motmots)
	Meropidae (bee-eaters)
	Leptosomatidae (cuckoo-roller)
	Coraciidae (rollers)
	Upupidae (hoopoe)
	Phoeniculidae (woodhoopoes)
	Bucerotidae (hornbills)
Piciformes	Galbulidae (jacamars)
	Bucconidae (puffbirds)
	Capitonidae (barbets)
	Indicatoridae (honeyguides)
	Ramphastidae (toucans)
	Picidae (woodpeckers, piculets, wrynecks)
Apterygiformes	Apterygidae (kiwis)
Passeriformes	Tyrannidae (tyrant flycatchers)
	Alaudidae (larks)
	Hirundinidae (swallows)
	Corvidae (jays, crows, magpies)
	Paridae (titmice)
	Sittidae (nuthatches)
	Certhiidae (Holarctic treecreepers)
	Pycnonotidae (bulbuls)
	Troglodytidae (wrens)
	Mimidae (mockingbirds)
	Muscicapidae (thrushes, accentors, babblers, etc.)
	Regulidae (kinglets)
	Motacillidae (pipits, wagtails)
	Bombycillidae (waxwings, silky flycatchers)
	Laniidae (shrikes)



Table 4. Class, Order and Family for Test Species	
Order	Family
	Sturnidae (starlings)
	Vireonidae (vireos, pepper shrikes)
	Parulidae (wood Warblers)
	Icteridae (American blackbirds)
	Emberizidae (tanagers, buntings, New World sparrows)
	Ploceidae (weavers, widow birds, Old World sparrows)
	Eurylaimidae (broadbills)
	Menuridae (lyrebirds)
	Atrichornithidae (scrub-birds)
	Furnariidae (ovenbirds)
	Dendrocolaptidae (woodcreepers)
	Formicariidae (antbirds)
	Pittidae (pittas)
	Pipridae (manakins)
	Cotingidae (cotingas)
	Conopophagidae (gnateaters)
	Rhinocryptidae (tapaculos)
	Oxyruncidae (sharpbill)
	Phytotomidae (plantcutters)
	Xenicidae (New Zealand wrens)
	Philepittidae (sunbird astites)
	Campephagidae (cuckoo-shrikes)
	Irenidae (leafbirds)
	Prionopidae (helmet shrikes)
	Vangidae (vanga shrikes)
	Dulidae (palmchat)
	Cinclidae (dippers)
	Aegithalidae (long-tailed tits)
	Remizidae (penduline tits)
	Climacteridae (Australasian treecreepers)
	Rhabdornithidae (Philippine treecreepers)
	Zosteropidae (white-eyes)
	Dicaeidae (flowerpeckers)
	Pardalotidae (pardalotes or diamond eyes)
	Nectariniidae (sunbirds, spiderhunters)
	Meliphagidae (honeyeaters)
	Ephthianuridae (Australian chats)
	Fringillidae (Hawaiian honeycreepers, cardueline finches)
	Estrildidae (waxbills)
	Oriolidae (orioles, figbirds)
	Dicruridae (drongos)
	Callaeidae (New Zealand wattlebirds)

Table 4. Class, Order and Family for Test Species	
Order	Family
	Grallinidae (magpie larks)
	Corcoracidae (Australian mudnesters)
	Artamidae (wood swallows)
	Cracticidae (bell magpies)
	Ptilonorhynchidae (bowerbirds)
	Paradisaeidae (birds of paradise)
<b>ML - Mammalia</b>	
Monotremata	Ornithorhynchidae (platypus)
	Tachyglossidae (echidnas or spiny anteaters)
Didelphimorphia	Didelphidae (New World opossums)
Paucituberculata	Caenolestidae (rat opossums, shrew opossums)
Microbiotheria	Microbiotheriidae (Monitos del monte)
Dasyuromorphia	Dasyuridae (native cats, marsupial mice)
	Myrmecobiidae (numbat, marsupial anteater)
	Thylacinidae (Tasmanian wolf)
Peramelemorphia	Peramelidae (bandicoots and bilbies)
	Peroryctidae (Spiny bandicoots)
Notoryctemorphia	Notoryctidae (marsupial moles)
	Acrobatidae (feathertail gliders)
Diprotodontia	Burramyidae (pygmy possums)
	Macropodidae (kangaroos and wallabies)
	Petauridae (gliders, striped possums)
	Phalangeridae (brushtail possums, cuscuses)
	Phascolarctidae (koalas)
	Potoroidae (rat kangaroos)
	Pseudocheiridae (ringtailed possums)
	Tarsipedidae (honey possums)
	Vombatidae (wombats)
Insectivora	Erinaceidae (hedgehogs and gymnures)
	Talpidae (moles)
	Solenodontidae (solenodons, almiquis)
	Tenrecidae (tenrecs)
	Chrysochloridae (golden moles)
	Nesophontidae (nesophontid insectivores)
	Soricidae (shrews)
Macroscelidea	Macroscelididae (elephant shrews)
Scandentia	Tupaiaidae (tree shrews)

Table 4. Class, Order and Family for Test Species	
Order	Family
Dermoptera	Cynocephalidae (colugos or "flying lemurs")
Chiroptera	Pteropodidae (Old World fruit bats, flying foxes)
	Rhinopomatidae (long-tailed or mouse-tailed bats)
	Craseonycteridae (bumblebee bat)
	Emballonuridae (sac-winged or sheath-tailed bats)
	Nycteridae (slit-faced or hollow-faced bats)
	Megadermatidae (false vampire bats)
	Rhinolophidae (horseshoe bats or Old-World leaf-nosed bats)
	Noctilionidae (bull-dog or mastiff bats)
	Mormoopidae (naked-backed bats, moustached bats)
	Phyllostomidae (New World leaf-nosed bats)
	Natalidae (funnel-eared or long legged bats)
	Furipteridae (smoky or thumbless bats)
	Thyropteridae (disc-winged bats)
	Myzopodidae (old world sucker-footed bats)
	Vespertilionidae (evening bats)
	Mystacinidae (New Zealand short-tailed bats)
	Molossidae (free-tailed bats)
Xenarthra	Dasypodidae (armadillos)
	Myrmecophagidae (anteaters)
	Bradypodidae (3-toed sloths)
	Megalonychidae (megalonychid sloths)
Pholidota	Manidae (pangolins)
Lagomorpha	Ochotonidae (pikas)
	Leporidae (hares and rabbits)
Rodentia	Aplodontidae (mountain beaver)
	Sciuridae (squirrels, chipmunks, marmots)
	Castoridae (beavers)
	Geomyidae (pocket gophers)
	Heteromyidae (kangaroo rats, pocket mice)
	Cricetidae (field mice, voles, lemmings, muskrats)
	Zapodidae (jumping mice)
	Spalacidae (mole rats)
	Rhizomyidae (bamboo rats)
	Dipodidae (jerboas)
	Muridae (Old World rats and mice)

Table 4. Class, Order and Family for Test Species	
Order	Family
	Anomaluridae (scaly-tailed squirrels)
	Pedetidae (cane jumping hare)
	Ctenodactylidae (gundis)
	Myoxidae (dormice)
	Bathyergidae (African mole rat)
	Hystriidae (Old World porcupines)
	Petromuridae (rock or dassie rat)
	Thryonomyidae (cane rat)
	Erethizontidae (New World porcupine)
	Chinchillidae (chinchillas, viscachas)
	Dinomyidae (pacarana or giant rat)
	Caviidae (guinea pigs, cavies)
	Hydrochaeridae (capybara)
	Dasyproctidae (agoutis, acuchis)
	Agoutidae (pacas)
	Ctenomyidae (tuco-tucos)
	Octodontidae (octodonts, degus)
	Abrocomidae (chinchilla rats)
	Echimyidae (spiny rats, rock rats)
	Capromyidae (hutias, coupus)
	Heptaxodontidae (giant hutias)
	Myocastoridae (coypus)
Cetacea	Balaenidae (right and bowhead whales)
	Neobalaenidae (pygmy right whale)
	Balaenopteridae (rorquals)
	Eschrichtiidae (gray whale)
	Physeteridae (sperm whale)
	Monodontidae (narwhal and white whale)
	Ziphiidae (beaked whales)
	Delphinidae (ocean dolphins)
	Phocoenidae (porpoises)
	Platanistidae (river dolphins)
Carnivora	Canidae (dogs, foxes, wolves, jackals)
	Ursidae (bears, giant panda)
	Otariidae (eared seal)
	Odobenidae (walrus)
	Procyonidae (racoons, lesser panda)
	Mustelidae (weasels, otters, skunks, badgers, minks)
	Phocidae (earless seals)
	Viverridae (civets)
	Herpestidae (mongooses)

Table 4. Class, Order and Family for Test Species	
Order	Family
	Hyaenidae (hyaenas)
	Felidae (cats)
Tubulidentata	Orycteropodidae (aardvark)
Proboscidea	Elephantidae (elephants)
Hyracoidea	Procaviidae (hyraxes)
Sirenia	Dugongidae (dugongs)
	Trichechidae (manatees)
Perissodactyla	Equidae (horses)
	Tapiridae (tapirs)
	Rhinocerotidae (rhinos)
Artiodactyla	
	Tayassuidae (peccaries)
	Hippopotamidae (hippopotamuses)
	Camelidae (camels, llamas)
	Tragulidae (chevrotains)
	Giraffidae (giraffe, okapi)
	Moschidae (musk deer)
	Cervidae (deer)
	Antilocapridae (pronghorn)
	Bovidae (cattle, goats, sheep, antelopes, gazelles)

### **Organism Source**

The source of the test organism is selected from the pull down list. A detailed description of each organism source is available under the description link to the right of the pull down list. The list of available organism sources is also provided in Table 5.

Table 5. Organism Source Code	
Code	Organism Source Description
CBC	Captive Breeding Colony
COM	Commercial Source
DOM	Domestic Strain
GAM	Game Farm Strain
GOV	Government Agency Source
LAB	Laboratory Strain
NR	Not Reported
WLD	Wild Strain

### **Control Type**

Criteria for effects of contaminant exposure are evaluated by comparing the exposed organisms to untreated organisms - the controls. The User selects the type of test control(s) used in the study from

the pull down list. Detailed descriptions of the available control types are available under the description link to the right of the pull down list. The list of available control types is also provided in Table 6. If the study reports multiple controls, select "M" for Multiple and briefly describe the control types in the comments text box provided. Studies which use Control types coded as historical (H), K, P, V, Z and NR are considered to be absent of an acceptable control group and are not used for the derivation of Wildlife TRVs.

Table 6. Control Type Code Descriptions	
B	<b>Baseline or Background Control:</b> parameters of actual or representative test species measured before and after administration of test contaminant, though not as part of the same test scenario. Note: pretreatment values, collected during the same test scenario as the observed responses, are recorded as
C	<b>Concurrent Control:</b> controls are run simultaneously with the exposure, e.g. in the laboratory where a contaminant free test chamber is used or in field studies where the control data are obtained upstream from the exposure data; also includes field tests where the controls are run in a separate system, i.e..
H	<b>Historical Control:</b> applicable to natural field system testing, data collected prior to exposure often during an independent long-term survey of the area; see also B - Baseline
K	Data for control are presented, but without accompanying methodology to identify procedures used
M	Multiple controls were reported, e.g. historic and concurrent
P	Positive controls were used
V	Carrier or solvent; organisms exposed to carrier or solvent as the only control
Z	No controls were used in the study
NR	Not reported; there is no information about presence or absence of controls in the publication

### **Number of Concentrations or Doses Tested**

The total number of different concentrations or doses administered to the test organism is entered for the specific Phase in the numeric field provided. The total number of concentrations (or doses) includes

the control(s). For example, for a study which has five exposure groups of 5, 10, 20, 50 mg/kg and a concurrent control, the number 5 would be entered.

### **Test Concentrations/Test Doses with Units**

The test ***concentration*** is the amount of contaminant to which the test organism is exposed per unit of exposure media (water, diet or other dose vehicle). The test ***dose*** is the amount of contaminant to which the test organism is exposed per unit of body weight in a specified period of time. For the purposes of establishing a wildlife TRV, doses are preferred over concentrations, but they are not reported in many toxicological studies.

If only exposure concentrations are reported in the study, the User **should not** calculate the respective dose. The application is designed to calculate the dose automatically based on the reported concentrations and User-supplied body weight and ingestion rate parameters. The User should enter in this field either the reported exposure concentrations **OR** doses, but not both. The concentrations or doses are separated by a forward-slash in the text box provided. The control(s) should be included as the first in the series (eg.: 0 / 5 / 10 / 20 / 50). The second portion of this field allows the User to select the appropriate concentration (or dose) units from the pull down list. A detailed description of the available units is provided under the description link to the right of the pull down list. The list of available units is also provided as Table 7.

<b>Table 7. Concentration Units and Conversions to Dose</b>			
<b>Concentration Fields</b>		<b>Conversion to Concentration (C) as mg/kg or mg/L</b>	<b>Conversion to Dose as mg/kg BW/day</b>
% in diet	percent in diet	multiply by 10000	Multiply C by the IR (kg/day) and divide by BW in kg
g/g	grams per g	multiply by 1,000,000	Multiply C by IR (kg/day) and divide by BW in kg
g/kg	grams per kilogram	multiply by 1,000	Multiply C by IR (kg/day) and divide by BW in kg
g/kg/d	grams per kilogram per day	multiply by 1,000	Multiply C by IR (kg/day) and divide by BW in kg
g/L	grams per liter	multiply by 1,000	Multiply C by IR (kg/day) and divide by BW in kg
mg/g	milligrams per gram	multiply by 1,000	Multiply C by IR (kg/day) and divide by BW in kg
mg/kg	milligrams per kilogram	multiply by 1	Multiply C IR (kg/day) and divide by BW in kg
mg/kg/d	milligrams per kilogram per day	multiply by 1	Multiply C by IR (kg/day) and divide by BW in kg
mg/l	milligrams per liter	multiply by 1	Multiply C by IR (kg/day) and divide by BW in kg
ng/g	nanograms per gram	multiply by 0.001	Multiply C by IR (kg/day) and divide by BW in kg

Table 7. Concentration Units and Conversions to Dose			
Concentration Fields		Conversion to Concentration (C) as mg/kg or mg/L	Conversion to Dose as mg/kg BW/day
ng/kg	nanograms per kilogram	multiply by 0.000001	Multiply C by IR (kg/day) and divide by BW in kg
ng/l	nanograms per liter	multiply by 0.000001	Multiply C by IR (kg/day) and divide by BW in kg
ng/mg	nanograms per milligram	multiply by 1	Multiply C by IR (kg/day) and divide by BW in kg
ppb	parts per billion	multiply by 0.001	Multiply C by IR (kg/day) and divide by BW in kg
ppm	parts per million	multiply by 1	Multiply C by IR (kg/day) and divide by BW in kg
ug/g	micrograms per gram	multiply by 1	Multiply C by IR (kg/day) and divide by BW in kg
ug/kg	micrograms per kilogram	multiply by 0.001	Multiply C by IR (kg/day) and divide by BW in kg
ug/l	micrograms per liter	multiply by 0.001	Multiply C by IR (kg/day) and divide by BW in kg
ug/mg	micrograms per milligram	multiply by 1000	Multiply C by IR (kg/day) and divide by BW in kg
Other	User defined	User defined	User defined

Table 8. Dose Units and Conversion to mg/kg BW/day		
Dose Fields		Conversion to mg/kg BW/day
g/d	grams per day	multiply by 1,000 then divide by BW in kg
g/g BW	grams per gram body weight	multiply by 1,000,000
g/kg BW	grams per kilogram body weight	multiply by 1,000
g/kg BW /d	grams per kilogram body weight per day	multiply by 1,000
g/org	grams per organism	multiply by 1,000 then divide by BW in kg
g/org/d	grams per organism per day	multiply by 1,000 then divide by BW in kg
kg/d	kilograms per day	multiply by 1,000,000 and divide by BW in kg
kg/org	kilograms per organism	multiply by 1,000,000 and divide by BW in kg
kg/org/d	kilograms per organism per day	multiply by 1,000,000 and divide by BW in kg
mg/d	milligrams per day	divide by BW in kg
mg/g BW	milligrams per gram body weight	multiply by 1000
mg/g BW/d	milligrams per gram body weight per day	multiply by 1000
mg/kg BW	milligrams per kilogram body weight	multiply by 1
mg/kg BW/d	milligrams per kilogram body weight per day	multiply by 1
mg/org	milligrams per organism	divide by BW in kg
mg/org/d	milligrams per organism per day	divide by BW in kg
ng/kg BW	nanograms per kilogram body weight	multiply by 0.000001



Table 8. Dose Units and Conversion to mg/kg BW/day		
Dose Fields		Conversion to mg/kg BW/day
ng/kg BW/d	nanograms per kilogram body weight per day	multiply by 0.000001
ng/org	nanograms per organism	multiply by 0.000001 and divide by BW in kg
ug/kg BW	micrograms per kilogram body weight	multiply by 0.001
ug/kg BW/d	micrograms per kilogram body weight per day	multiply by 0.001

In cases where the reported concentration or dose units are not provided, the User is required to convert the reported results (NOAEL, LOAEL dose or concentration) to one of the units available for selection. If the units are reported as concentration per animal or unit body weight per unit of time, other than days it is necessary for the User to convert to concentration (or dose) per day. An example is provided in the following text box.

### **Are Absorbed Doses Reported?**

An absorbed dose is defined as the amount of the exposure dose which is absorbed into the bloodstream. For example, if 80 percent of an exposure dose of 10 mg/kg BW/day is absorbed, the absorbed dose is 8 mg/kg BW/day. Absorbed doses are not typically reported in toxicity studies. Select "Yes" or "No" by checking the appropriate box. If "Yes" is selected, the User enters a brief description of how the absorbed doses were measured and reported in the text box provided.

#### **Example for Conversion to Appropriate Concentration or Dose Units**

A study reports a NOAEL dose administered as 10 ug per animal every two days. The User needs to convert this dose to any set of units that can be entered into the application. The User selects to convert the dose to mg per day by multiplying the dose by a conversion factor for ug to mg of 0.001 and dividing by 2 to achieve an administered concentration of 0.005 mg per day. The User can now enter this result and select the mg per day units from the dose fields. The User should enter the conversions in detail in the comment field provided.

### **Method of Contaminant Analysis**

Within this field, the User identifies if the test exposure concentrations (or doses) are quantified or if nominal values are reported. For the specific exposure level, the User reports the method of contaminant analyses from the pull down list provided. A detailed description of each method of analysis is available under the "Description" link to the right of the pull down list. The list of available contaminant analysis methods is shown in Table 9. If the method of contaminant analyses is not clear from the information provided in the study, then the User selects "NR" for Not Reported. To complete this entry, the User should carefully read the text of the paper to discern if exposure concentrations in the diet or drinking water are verified by contaminant analyses. Some studies that verify or measure the concentration or doses administered provide this information in the text of the paper, but do not report the measured dose intervals.

Table 9. Method of Contaminant Analysis Code Descriptions	
Code	Method of Contaminant Analysis Description
Measured (M)	Exposure and/or observation concentrations or doses are quantitative; analysis methods may be reported; note that exposure concentrations may be analyzed but observations could be reported in terms of nominal, unmeasured values. This distinction must be noted when coding.
Unmeasured (U)	Exposure and/or observation concentrations or doses are clearly identified as nominal values; or when the author does not report any information about whether the concentrations were measured or nominal, ie. unmeasured is used as a default value when there is no information provided about the contaminant concentrations.
Calculated (C)	Exposure and/or observation concentrations or doses are estimated through calculation rather than quantitative measurement.
Not Reported (NR)	Exposure and/or observation concentrations or doses are reported as both the measured and the unmeasured values but it is not clear whether the observation/response dose is a measured or nominal value.

### Measured Concentrations/Measured Doses with Units

The measured *concentration* is the amount of the contaminant analyzed in the exposure medium or media. The measured *dose* is the amount of contaminant analyzed in the exposure media per unit of organism (amount of contaminant per unit body weight or per organism) in a specified period of time. For the purposes of establishing the TRV, doses are preferred over concentrations. If only concentrations are reported in the study, the User **does not** calculate the respective dose. The application is designed to calculate the dose automatically. Within this field, the User enters either the measured concentrations **OR** doses (not both) for each of the treatment groups separated by a forward-slash in the text box provided. The control(s) are included first in the series. (eg.: 0.2 / 4.8 / 10.2 / 18.9 / 51.1). The User next selects the appropriate units associated with the measured concentrations or doses reported in the study from the pull down list. A detailed description of available units is provided under the description link to the right of the pull down list. The list of available units is also provided as Table 7.

### Application Frequency

The frequency of the exposure application is selected from the pull down list. For exposures in which there are "X" applications per a given time period, the User enters the number of applications in the numerical field provided. A detailed description of the selections available for application frequency is available under the description link to the right of the pull down list. The list of available application frequency selections is also provided in Table 10a.

Table 10a. Application Frequency Code Descriptions	
ADL	Ad libitum; without limit or restraint
CON	Continual; non-pulsed
DLY	Daily; dosing regime not specified
EOD	Every other day
X	Dosed x time(s) per study period; e.g. 1 time = 1X
X per h	X times per hour
X per d	X times per day
X per w	X times per week
X per mo	X times per month
NR	Not Reported

## **Exposure Type**

The exposure type represents the method by which the contaminant is administered to the test organism. For the purposes of establishing the Wildlife TRVs, studies reporting results for oral exposures (diet, gavage, capsule and drinking water) are exclusively used. Studies reporting an exposure type other than oral should have been excluded earlier in the process in the application of the Literature Rejection Criteria described in Section 2. If the User at this point of the data entry process discovers a study reporting results for non-oral exposures, the information entered to this point is saved and the program exits to the "Data Entry" screen.

Table 10b. Exposure Type and Route of Exposure Code Descriptions			
Diet (D) Codes		Topical (T) Codes	
FD	contaminant incorporated into the	DM	dermal
DR	contaminant incorporated into the	MM	immersion
CH	choice of treated or untreated food or	NR	not reported
GV	gavage	PC	percutaneous
NR	not reported	SA	surface area dose
OR	oral eg. via capsule	SH	eggshell
		TP	topical, general
Injection (I) Codes		Environmental (V) Codes	
IJ	injection, unspecified	AG	aerial-granular
IC	intercutaneous	AS	aerial spray application
IG	intragastrical	DA	direct application
IM	intramuscular	EN	environmental, unspecified
IP	intraperitoneal	GG	ground granular
IR	intraprostomial	GS	ground spray
IS	intrasegmentally (insects)	HS	hand spray
IE	intratesticular	IN	in situ
IT	intratracheal	MT	multiple routes, eg. dermal,
IV	intravenous	NR	not reported
NR	not reported	PU	pump

Table 10b. Exposure Type and Route of Exposure Code Descriptions			
YK	yolk	SP	spray
		SS	Soil slurry
<b>Inhalation (N) Codes</b>			
IH	Inhalation		
NR	Not reported		

### **Route of Exposure**

The route of exposure is directly related to the "Exposure Type" as described in Table 10b. Because the Wildlife TRVs are based only on data from oral exposure studies, only codes specific to oral exposures are available in the pull down list.

### **Test Location**

The User selects the appropriate location or setting in which the experiment is reported to be conducted from the pull down list. The list of test locations and definitions is provided in Table 11. If the test location is not specified, the User is instructed to select "NR" for Not Reported.

Table 11. Test Location Code Descriptions	
FieldA*	<b>Field, Artificial</b> - a simulated or artificial field study is conducted in "an artificially bounded system that is a simplification of a specific ecosystem", e.g., aviaries, pens, enclosures
FieldN*	<b>Field, Natural</b> - a natural field study is one "in which both the test system [...] and exposure to the stressor are "naturally" derived"; e.g., sprayed agricultural field or orchard plots, field surveys
FieldU*	<b>Field - Unable</b> to determine whether natural or artificial setting
Lab*	<b>Laboratory</b> indoor setting
NR*	<b>Not Reported</b> - unable to determine if laboratory or field

\* Rand 1995

### **Experimental Design**

The User enters a brief description of the experimental design in the text box provided. The experimental design description includes, but is not limited to, information specific to dosing design, control groups, exposure durations, and test organisms.

## Test Conditions

A checklist of standard guidelines and reporting parameters for toxicological studies is provided as Table 12. The User evaluates the information reported in the study pertaining to test conditions. The comparison is based on standard reporting parameters for 16 standard toxicological test protocols. The User chooses the appropriate selection from the pull down list based on the test conditions and parameters reported in the study.

Table 12. Standard Study Guidelines and Reporting Parameters								
Test Conditions	Test Protocols							
	Avian Dietary	Avian Reproduction	90 day Oral Study in Rats	Chronic Oral Study in Rats	Subacute Dietary with Avian Species	Reproductive Studies with Avian Species	Developmental Toxicity in Rats and Rabbits	Reproduction and Fertility Study in Rats
	OPPTS 850.2200	OPPTS 850.2300	ASTM E 1372-95	ASTM E 1619-95	ASTM E 857-87	ASTM E 1062-86	ASTM E 1062-86	ASTM E 1062-86
Source of Test Animals	X	X	X	X	X	X	X	X
Health of Test Animals	X	X	X	X	X	X	X	X
Age of Test Animals	X	X	X	X	X	X	X	X
Acclimation procedures	X	X	X	X	X	X	X	X
Assignment of animals to housing	X	X	X	X	X	X	X	X
Description of basal diet (including source, diluents and supplements)	X	X	X	X	X	X	X	X
Nutrient content of diet	X	X	X	X	X	X	X	X
Water	X	X	X	X	X	X	X	X
Description of housing conditions (including size, type, material)	X	X	X	X	X	X	X	X
Temperature	X	X	X	X	X	X	X	X
Photoperiod	X	X	X	X	X	X	X	X
Lighting intensity	X	X	X	X	X	X	X	X
Humidity	X	X	X	X	X	X	X	X
Frequency, duration and methods of observation	X	X	X	X	X	X	X	X
General description of facilities	X	X	X	X	X	X	X	X
Description of test substance (including CAS number, purity, source, solvent or carrier, if used.)	X	X	X	X	X	X	X	X

The "Exposure Information" screen is now complete. The User now verifies that all data entered are correct and click on "Next" at the bottom of the screen to continue. The User **may not** use the back

arrow to return to a previous data entry screen to correct errors. Using the back arrow results in deletion of information.

#### 4.4 Endpoint Information

##### Exposure Duration and Units

The exposure duration is entered for the specific endpoint in the numeric field provided. For example, if a study's contaminant exposure lasts for ten weeks, the User enters the number 10. For studies that report dosages (or concentrations) that are varied during the period of exposure, the User evaluates each unique dosage duration as a separate endpoint. The units associated with the exposure duration are selected from the pull down list provided. The list of available units is also shown as Table 13.

For multi-generation studies which evaluate endpoints specific to both the mother and progeny, the User enters the age, sex, and lifestage associated with the endpoint of concern. For example, for a maternal endpoint, such as body weight of mother, number of litters, litter survival, or progeny weight, the User enters the age, sex, and lifestage of the mother. For a progeny endpoint such as pup growth or learning behavior, information for the offspring is entered (age, sex and lifestage).

##### **Coding Multi-Generation and Prenatal Exposure Studies**

###### Multi-Generation Studies

- Enter the number of generations
- Enter "lf" for life time
- Enter results for the last generation or the most sensitive generation

###### Gestational Exposures

- Enter results as separate Phases for mother and progeny
- For mothers enter exposure time during gestation. If exact time is not reported estimate based on gestation of test animal.
- For progeny enter units as "-n" pretreatment time.

**Table 13. Exposure Duration and Age Units**

s	second
mi	minute
h	hour
d	day
w	week
mo	month
yr	year
lf	lifetime
-n	pretreatment time
-x	pretreatment response observation but time unknown
/	duration is qualitative; information is recorded as text
NR	Not Reported

### **Age with Units**

The age of the test organism at the beginning of the study for the specific endpoint is entered in the numeric field provided. For example, if the study reports that two week old ducklings are exposed at the start of the study, the User enters the number 2. Next, the appropriate units are selected from the pull down list provided. The list of available age units is also shown in Table 13. The age units are equal to the exposure durations and units.

### **Sex**

The User selects the sex of the test organism from the pull down list provided. If the sex of the test organism is male, then "M" is selected for male. If the sex of the test organism is female, then "F" is selected for female. If the sex of the test organism is specified as both male and female, then "BH" is selected for "Both Male and Female". If the sex is not specified, then "NR" is selected for Not Reported.

### **Lifestage**

The lifestage of the test organism is selected from the pull down list provided. The list of available lifestages is shown as Table 14. If the lifestage of the test organisms is not reported or evident from the study, then "NR" is selected for Not Reported. For possible future applications, the pull down list includes lifestages for terrestrial insects including larvae (LV), nauplii (NU) and pupa (PU), which do not apply to the coding process for Wildlife TRVs.

### **Is this a Critical Lifestage?**

A lifestage is defined as critical if it is critical to the survival and reproduction of the species. These lifestages may or may not be more sensitive to contaminant exposure. Exposures during these critical lifestages are preferred in the derivation of wildlife TRVs. Table 14b identifies the lifestages from the pull down list considered to be "critical". The User selects "Yes" or "No" by checking the appropriate box. If the lifestage is not specified, the User should check "NR" for Not Reported. There may be some cases where the User can use professional judgement to classify certain exposures as critical. Critical exposures would include those during lactation and gestation.

Table 14. Lifestage Code Descriptions		
Code	Lifestage	Critical (Yes or No)
AD	adult	No
EG	egg	Yes
EM	embryo	Yes
IM	immature	Yes

Table 14. Lifestage Code Descriptions		
Code	Lifestage	Critical (Yes or No)
JV	juvenile; includes yearling, fledgling, hatchling, weanling	Yes
MA	mature	No
MU	multiple	Yes
NR	not reported, unknown	No
SA	subadult	No
SI	sexually immature	No
SM	sexually mature	No
YO	young	Yes
YY	young of year	Yes
	Gestational Exposures	Yes
	Lactation	Yes
	Other (User Defined)	

## **Effect Group**

Contaminant exposures to test organisms can result in both positive and adverse effects. The possible adverse effects that may be reported in toxicological studies are divided into nine Effect Groups developed as part of the coding system devised for EcoTox by EPA Duluth. The Effect Groups include accumulation (ACC), behavior (BEH), biochemistry (BIO), growth (GRO), mortality (MOR), pathology (PTH), physiology (PHY), population (POP), and reproduction (REP). A brief description of each effect group is available under the description link to the right of the pull down list. The list of available Effect Groups is also provided as Table 15.

The User selects the appropriate effect group from the pull down list provided. The User should consult both Tables 15 and 16, which provide the Effect Types and Measures that are specific to the Effect Groups to identify the appropriate Effect Group for the endpoint described in the study under review.

Table 15. Effect Group Descriptions	
ACC	<b>Accumulation:</b> a general term describing the process (bioaccumulation) by which contaminants are taken into and stored in plants or animals; bioaccumulation occurs when the rate of contaminant uptake exceeds the rate of elimination of the same contaminant; therefore accumulation measurements include uptake (UPTK) and elimination (ELIM) rates as well as actual tissue concentrations (RSDE); accumulation endpoints include the asymptotic threshold concentration (ATCN), bioconcentration factor (BCF) and bioaccumulation factor (BAF).
BEH	<b>Behavior:</b> a general term characterizing overt activity of an organism represented by three effect groups - avoidance, general behavior, and feeding behavior. Behavioral measurements include stimulus avoidance (STIM), feeding changes (FDNG), general reproductive success (RSUC), and general activity levels (ACTV).



Table 15. Effect Group Descriptions	
BIO	<b>Biochemical:</b> measurement of biotransformation or metabolism of chemical compounds, modes of toxic action, and biochemical responses in plants and animals including three effect groups - chemical, enzyme and hormone effects. Biochemical measurements include chemical parameters such as cell (CCHG) or amino acid (AMAC) changes, enzyme parameters such as transferase, oxidase or hydrolase reactions, and measurements of hormone response levels. Biochemical endpoints include EDxx, ID50, NOEL and LOEL.
GRO	<b>Growth:</b> a broad category which encompasses measures of weight and length and includes effects on development, growth and morphology. Morphology: measurements and endpoints which address the structure (bones) and form (organ/tissue development) of an organism, or plant, at any stage of its life history.
MOR	<b>Mortality:</b> measurements and endpoints where the cause of death is by direct action of the contaminant; e.g. an endpoint such as the LD50 estimates the lethal dose to 50% of the exposed population whereas measurements count the actual number dead or the percentage reduction within a population as a result of the exposure.
PTH	<b>Pathology:</b> measurements and endpoints regarding the causes, nature and effects of diseases and other abnormalities; the four effect groups include histology, immunotoxicity, intoxication and parasites.
POP	<b>Population:</b> measurements and endpoints regarding a group of organisms or plants of the same species occupying the same area at a given time. Measurements include abundance, biomass, size and age class structures.
PHY	<b>Physiology:</b> measurements and endpoints regarding changes and activity in cells and tissues of plants or animals.
REP	<b>Reproduction:</b> measurements and endpoints to track the effect of toxicants on the reproductive cycle.

### Effect Type

The available Effect Types in the pull down list are directly related to the Effect Group that the User selects first. The appropriate Effect Type for the endpoint is selected from the pull down list provided. The available selections are listed in Table 16.

### Effect Measure

The effect measure is a variable used to interpret the degree of an organism response to contaminant exposure. The available Effect Measures in the pull down list are directly related to the Effect Type selected above. The User selects the Effect Measure from the pull down list. The list of available selections is provided in Table 16. To avoid repetitive entries of NOAEL and LOAEL values and to make the coding process more efficient, the User is instructed to record only **one result** per Effect Type. The most conservative result (lowest NOAEL or LOAEL) should be recorded.

Table 16. Effect Groups, Types and Measures			
Effect Group	Effect Type	Effect Measures	
BEH	AVO (avoidance)	CHEM- contaminant avoidance	STIM - stimulus avoidance
		FOOD - food avoidance	WATR - water avoidance
BEH	BEH (general behavior)	ACTP accuracy of learned task,	NMVM - number of movements
		ACTV - activity, general	PRDC - production, general
		BLNC - balance	RSPT - response time to stimulus

Table 16. Effect Groups, Types and Measures			
Effect Group	Effect Type	Effect Measures	
		BHVR - behavioral changes	RRSP - righting response
		DPLY - displaying behavior	INST - sleeping time, induced
		DIST - distance	VCLF - visual cliff
		DRMT - dormant, adverse	NVOC - vocalizations, number of
		FRZG - freezing behavior	
BEH	FDB (feeding behavior)	BGNB - begging behavior	FCNS - food consumption
		FDNG - feeding behavior	FSTR - food storage
		FEFF - feeding efficiency	WCON - water consumption
		FTIM - feeding time	

Table 16. Effect Groups, Types and Measures			
Effect Group	Effect Type	Effect Measures	
BIO	CHM (chemical)	ALBE -albumen energy	LEUC - leucine
		ALB - albumins	LEUK - leukocytes
		ACHL - acetylholinesterase	LIPD - lipid
		ESAA - amino acids, essential	LMPH - lymphocyte
		AMAC - amino acids, general	LPSA - lipid soluble antioxidants
		TTAA - amino acids, total	LYSI - lysine
		TFAA - amino acids, total free	MCHC - mean corpuscular
		NEAA - amino acides,	MCPV - mean corpuscular volume
		AMMO - ammonia	METH - methionine
		ANBC - aniline binding capability	MCPR - microsomal proteins
		ALAN - alanine	MONO - monocyte
		AABA - alpha-aminobutyric acid	NADP - nicaninamide-adenine
		ARGI - arginine	ORNI - ornithine
		ASHC - ash content	OSRS - osmotic resistance/RBC
		ASPA - apartate	PCLV - packed cell volume
		BASO - basophil	AMNH - p-amino hippurate
		TLBL - bilirubin, total	PHPH - pH
		BIOT - biotin content	PHEN - phenyalanine
		BUNT - blood urea nitrogen	PPHT - phosphate
		BDVL - blood volume	PHSP - phospahtide phosphorus
		CALC - calcium	PHOS - phosphorus
		CAPH - calcium/phosphorus ratio	PORP - porphyrin
		CCHG - cell changes	POTA -potassium
		CHOL - cholesterol	TOPR - protein, total
		CHLN - choline	PRT0 - protoporhyrin
		CHLR - chloride	PYRV - pyruvate
		CREA - creatinine	RGSH - reduced glutathione
		CYB5 - cytochrome B-5	NPSH - nonprotein sulfhydryl
		P450 - cytochrome P450 proteins	RBCE - red blood cell
		DISC - dethylsuccinate hdyrolysis	RBVL - relative blood volume
		DTBL - direct bilirubin	RETI - reticulocytes
		EOSN - eosinophil	SERI - serine
		ERTH - erythoroblasts	SRTN - serotonin
		FFTA - fatty acids, free	SODI - sodium
		NEFA - fatty acids, nonesterified	SPLO - splenocytes
		GLUC - glucose	TEAM - tetraethylammonium
		GMIN - glutamine	THBA - thiobarbituric acid
		GLCN - glycine	THRE - threonine
		GLYC - glycogen	THRM - thrombocytes
		HMCT- hematocrit (anemia)	TRIB - tributyrin
		HEME - heme content	TRIG - triglycerides

Table 16. Effect Groups, Types and Measures				
Effect Group	Effect Type	Effect Measures		
		HMGL - hemoglobin	TRYP - tryptophan	
		HIST - histidine	TYRO - tyrosine	
		5HAA - 5-hydroxyindole acetic	UREA - urea	
		IBIL - indirect bilirubin (free)	URIC - uric acid	
		ILEU - isoleucine	VALI - valine	
		NEUT - neutrophil	VTD3 - vitamin D3	
		LACT - lactate	UBWB - white blood cell,	
		LCTA - lactic acid	TWBC - white blood cell count,	
		LEAD - lead		
BIO	ENZ (enzyme)	20HB - 2-OH biphenyl	FDPA - fructos-diphosphate	
		40HB - 4-OH biphenyl	GGTR - (gamma) Y-	
		ACHE - acetylcholinesterase	G6PD - glucos-6-phosphate	
		ACPH - acid phosphatase	GLTR - glucouronyl transferase	
		AEPX - aldrin epoxidase	GLAD - glutamic acid	
		AHDX - aniline hydroxylase	GOTR - glutamic-oxaloacetic	
		ALAD - (delta) -aminolevulinic	GPTR - glutamic pyruvic	
		ALDO - aldolase	GLPX - gluathione peroxidase	
		ALPH - alkaline phosphatase	GSTR - glutathione S-transferase	
		ALAS - (gamma) y-ALA	GLRE - glutathione reductase	
		AATT - alanine aminotransferase	HXBH - hexobarbital	
		ATRP - alanine transpeptidase	LADH - lactate dehydrogenase	
		APND - aminopyrin n-	LDMD - lactate	
		AHHD - aryl hydrocarbon	MADH - malic dehydrogenase	
		ASAT - aspartate	MCOD - methoxycoumarin O-	
		BCHE - buterylcholinesterase	MG6P - microsomal glucose 6-	
		BCOD - butoxycoumurin O-	MAOA - mono amino oxidase	
		BIO	BAPH - benzo(a)pyrene	PNAD - p-nitroanisole
			BAPH - benzo(a)pyrene	ANAE - alpha naphthyl acetat
BPND - benzphetamine-n-	CYTC - NADPH cytochrome C			
BHXA - benzpyrene hydroxylase	450R - NADPH dehydrogenase			
BROD - benzylresorufin O-	DHYD - NADPH dehydrogenase			
CASE - calcium ATPase	ORCT - ornithine carbamoyl			
CAAH - carbonic anhydrase	PBHD - pentobarbital			
CACA - choline acetyltransferase	PROD - pentylresorufin O-			
CEST - chloinesterase	PBES - pehyl benzoate esterase			
CRKI - creatine kinase	PCOD - propoxycoumarin O-			
CCOX - cytochrome C-oxidase	SGOT - serum glutamate oxalo			
EPHY - epoxide hydrase	SGPT - serum glutamic pyruvic			
ECOD - ethoxycoumurin O-	NKAT sodium potassium			
EROD - 7-ethoxyresorufin O-	SBDH - sorbitol dehydrogenase			
ESTE - esterase	SCDH - succinate dehydrogenase			
TRIE - triacetin esterase	THTR - thio transferase			

Table 16. Effect Groups, Types and Measures			
Effect Group	Effect Type	Effect Measures	
BIO	HRM (hormone)	ANDR - androgen	HRMN - hormone, changes in
BIO	HRM (hormone)	ESDL - 17-beta estradiol	NORE - norephinephrine
		CORT - corticosterone	PROH - progeterone
		DOPA - dopamine	TSTR - testosterone
		EPIN - epinephrine	THYR - thyroxine
		ESTR - estrogen	TRII - tridothyronine
GRO	DVP (development)	EMDV - embryo development	LRGN - limb regeneration
		FLDG - fledged/female or /brood	WEAN - weaned
GRO	GRO (growth)	BODL - body length changes	BDWT - body weight changes
GRO	MPH (morphology)	COSC - caudal ossification center	RULT - radius-ulna length
		CRLT - crown-rump length	SHGR - shell growth
		FRLT - feather length	SOSC - sternal ossification center
		GMPH - general morphological	SRIB - supernumerary ribs
		HULT - humerus length	TRLT - tarsus length
		MOSC - metacarpal ossification	TELT - testis length
		OVLTL - oviduct length	TTLT - tiibiotarsus length
MOR	MOR (mortality)	HTCH - hatch	MORT - mortality
		TKNO - knockdown	SURV - survival
		MDTH - mean time of death	TDTH - time to death
PTH	ORW (Organ	SMIX - organ weight in	ORWT - organ weight changes
PTH	HIS (histology)	ARTS - arteriosclerosis	HEMR - hemorrhage
		EDMA - edema	HYPL - hyperplasia
		TFLR - tissue fluorescence in UV	CTYP - percent cell type
		GHIS - histological changes,	NCRO - necrosis
		GLSN - gross lesions	NPHR - nephrosis
PTH	ITX (intoxication)	USTR - ultrasctructural changes	INCO - incoordination
		ANOR - anorexia	IMBL - immobile
		ATAX - ataxia	INTX - intoxication, general
		CONV - convulsions	PARL - paralysis
PTH	IMM (immuno toxicology)	TINT - time to signs of	NKCA - natural killer cell activity
		ASHG - anti-sheep red blood cell hemagglutinin	PARA - amount or percent animals infested with parasites
		DHYP - delayed type	LYMP - lymphocyte activity
PTH	PRS (parasites)	THYM - thymocyte activity	
POP	POP (population)	PBMS - biomass or weight for	NCHG - population change
		DVRS - diversity	PDEN - population density
		EVEN - evenness	RCPR - recapture ratio
		INDX - index to population size,	SEXR - sex ratio
		NPOP - number of animals/population	
PHY	PHY (physiology)	TRAP - trappability	HYDR - hydration

Table 16. Effect Groups, Types and Measures			
Effect Group	Effect Type	Effect Measures	
		ADPO - oxidative	RPRT - respiratory rate
		BTMP - body temperature	SPOS - serum/plasma osmolality
		EECG - electroencephalogram	PRIN - PR intervals
		EXCR - excretion rate	SKIR - skin irritation
		HTRT - heart rate	THRG - thermoregulation
REP	REP	ABNM - abnormal	OBRD - open brood
		CYNG - care of young, nest	OVRT - ovulation rate
		NCLU - corpus lutea, number of	BNDG - pair bonding nesting
		COUR - courtship behavior	PLBR - pairs with litter or brood
		EGPN - eggs per nest	PRFM - pregnant females in a
		FERT - fertility	PIPD - pipped
		GIDX - gestation index	PROG - progeny counts/numbers
		GSTT - gestation time	PRWT - progeny weight (TBWT,
		LACT - lactating	RBEH - reproductive behavior
		NANT - nests abandoned	RPRD - reproductive capacity
		NSTI - nest initiation	RSUC - reproductive success
		NTSZ - nest size	RSEM - resorbed embryos
		NSTS - number of active nests	RBRD - sealed brood
		NDAY - number of days between	SPCL - sperm cell counts
		NINC - number of nests incubated	SPCV - sperm cell viability
		NSTS - number of active nests	TERA - teratogenic measurements
		NOPN - number of organisms per	TPRD - total production
		NSNT - successful nests	TEWT - testes weight
		NUNT - unsuccessful nests	TEDG - testes degeneration
		OEGP - onset of egg production	OTHR - other
REP	EGG	ALWT - albumen weight	ESWT - eggshell weight
		CREG - cracked eggs	ESWD - eggshell width
		EGVL - egg volume	FTEG - fertile egg
		EGWT - egg weight	SHLL - percent shell
		ESIN - eggshell index	SHSZ - shell size
		ESLT - eggshell length	SFYK - soft yolk
		ESQU - eggshell quality	YOLK - yolk, percent
		ESTH - eggshell thickness	YKWT - yolk weight

## **Response Site**

The response site is the specific location at which an effect is observed. The response site is not applicable for mortality (MOR), reproductive (REP) or behavioral (BEH) effects. The response site specific for the endpoint is selected from the pull down list. The list of available selections is provided in Table 17. If the response site is not reported, then "NR" is selected for Not Reported.

Table 17. Response Sites and Codes			
Code	Response Site	Code	Response Site
AG	Accessory Gland	LU	Lungs
AM	Adductor Muscle	MM	Mammary Tissue
AD	Adipose Tissue	MS	Mesenteric Lymph Node
AR	Adrenal Gland	MC	Microsome
AS	Air Sac	MI	Midgut and Midgut Gland
AL	Albumen (egg white)	MK	Milk, lactating females
AT	Alimentary Tract	MT	Multiple Tissue/Organs
AF	Amniotic Fluid	MU	Muscle
AP	Appendages	MB	Muscle+Bone
BI	Bile	MO	Mucous
BL	Blood	NG	Nasal Gland
BV	Blood Vessel	NE	Nervous Tissue
BO	Bone	NK	Neck
BM	Bone Marrow	NR	Not Reported
BR	Brain	OL	Olfactory
BT	Breast	OV	Ovaries
BC	Buccal mass	OD	Oviduct
BU	Bursa	PS	Pancreas
CA	Cartilage	PE	Penis
CH	Chord, spinal	PI	Pituitary Gland
CL	Claw	PC	Placenta
CG	Cloacal gland	PL	Plasma
CO	Collagen	PG	Prostrate Gland
CR	Crop	RC	Rectum
DG	Digestive Gland	RT	Reproductive Tissue
DT	Digestive Tract	RR	Residual, Remnant, Carcass
ET	Edible Tissue	RM	Retractor Muscle
EG	Egg	SC	Scale
EU	Egg Cuticle	SV	Seminal Vesicle
EM	Embryo	SE	Sensory Organs
EN	Entrails	SR	Serum
ER	Erythrocyte	SN	Skeleton
ES	Esophagus	SK	Skin, Epidermis
EC	Excreta	SM	Sperm
EX	Exoskeleton	SP	Spleen
EY	Eye	SH	Stomach
FE	Feathers	ST	Soft Tissue
FC	Feces	SX	Submaxillary Gland
FM	Femur	TA	Tail
FO	Foot	TE	Testes
GB	Gall Bladder	TG	Thigh muscle
GT	Gastrointestinal Tract	TB	Tibia
GZ	Gizzard	TI	Tissue
GO	Gonads	TS	Thymus

Table 17. Response Sites and Codes			
Code	Response Site	Code	Response Site
GU	Gut	TY	Thyroid
HA	Hair	UB	Urinary Bladder
HD	Head	UR	Urine
HE	Heart	UT	Uterus
HM	Humerus	VD	Vas Deferens
HY	Hypothalamus	VE	Vertebra
IN	Intestinal Tract	VI	Viscera
KI	Kidney	WI	Wings
LD	Lipid, Fat	WO	Whole Organism
LG	Leg	YO	Yolk
LI	Liver		

### **Endpoint Comments**

The endpoint comment field allows the User to enter any specific notes concerning the selected endpoint that has not previously been entered. Within this field, the User enters information specific to the selection of endpoints for data entry in cases where more than one effect measures for effect end.

### **Identify the NOAEL and or LOAEL**

The NOAEL is defined as the concentration (or dose) associated with no statistically significant adverse effects to the test organism. In some cases, statistics may not be provided with the results and the User is required to judge if the response is significant compared to controls. If enough information is provided, the User may apply appropriate statistics

In other cases, the statistical analyses used in a study may not be appropriate or adequate for the particular study design. In these cases, the reviewer has three choices. The first choice is to re-analyze the data with appropriate statistics and record the results. In the second case, the reviewer could decide on a NOAEL or LOAEL based on the preponderance of the data. Third the reviewer could reject the study and assign a data evaluation score of 0 in which case the study result would be rejected and not used in the derivation of wildlife TRVs..

The LOAEL is defined as the lowest concentration (or dose) at which statistically significant adverse effects are observed in the test organism compared to controls. The NOAEL and LOAEL are endpoint specific. For example, the selected LOAEL for a growth endpoint may be 5.7 mg/kg BW/day whereas the LOAEL for a pathological endpoint may be 2.3 mg/kg BW/day. Toxicological studies may report both a NOAEL and a LOAEL, only a NOAEL, or only a LOAEL.

In theory, the threshold for the particular adverse effect lies between the NOAEL and the LOAEL. A variety of recent studies have reviewed the weaknesses of the use of NOAELs in risk assessments (references). Some analyses of acute toxicity test have shown that NOAELs can represent as much as a



30% or 40% difference from control (due to low statistical power) while other studies have LOAELs that are incorrectly low due to statistical artifacts. While it is hoped that NOAELs and LOAELs bracket the threshold concentration, their determination is a function of the spacing of dietary concentration and the statistical power of the test.

The User is required to review the toxicological study and identify both NOAELs and LOAELs. The identification of the NOAEL and LOAEL is the most critical step in the data entry process. In cases where an apparent statistically-significant difference is reported at a lower dose but not at higher doses and/or there is anecdotal information that the apparent effect is a statistical artifact rather than a real effect, the User is instructed to identify a NOAEL instead of a LOAEL.

#### **NOAEL and LOAEL Units**

The units associated with the NOAEL and LOAEL are automatically assigned by the application based upon the units previously selected when describing the exposure concentrations or doses (see the Exposure Information section). If measured concentrations are entered, these units are preferentially returned as the units for the NOAEL field.

#### **Is the NOAEL or LOAEL Reported by the Author?**

If the NOAEL and/or the LOAEL are calculated and clearly stated by the author, then the User is instructed to select "Yes" by checking the appropriate box. If the NOAEL and/or LOAEL are assigned by the reviewer, based on information provided in tables or figures, the User selects "No" by checking the appropriate box.

#### **NOAEL and LOAEL Comments**

In the NOAEL/LOAEL comment field, the User enters any specific information pertaining to the selection of NOAEL and/or LOAEL values that has been previously entered in the text box provided.

#### **Is Wet Weight Reported?**

The Eco-SSL for wildlife is reported as a "safe concentration" in soil on a dry weight basis. The estimation (or back calculation) from a safe dose to an associated safe soil concentration requires the TRV to be expressed on a dry weight basis. This requires that the estimation of a dose (mg of contaminant per kg BW of the test organism per day) from dietary exposure concentrations be based on units per dry weight diet.

If the study reports that the dietary exposure concentrations are expressed on a wet weight basis, then the User should select "Yes" by checking the appropriate box. If the dietary concentration units are reported as dry weight, select "No" by checking the appropriate box. If the dietary concentration units are not specified as wet weight or dry weight, select "NR" for Not Reported. Also, select "Yes" if a

drinking water, gavage or other oral study is being entered. For studies where NR is entered the entered results are assumed to be reported in dry weight and are not converted by the application. This is assumed to be conservative as conversion to dry-weight results in higher LOAEL and NOAEL dose values.

### **If Wet Weight is Reported, Is the Percent Moisture Reported?**

If the dietary concentration level units are reported as wet weight and the percent moisture is also reported, the User selects "Yes" by checking the appropriate box. If percent moisture is not reported, the User selects "No" by checking the appropriate box. For drinking water studies, the User selects "Yes" by checking the appropriate box.

### **Percent Moisture (%)**

If the percent moisture in the exposure media is reported, the User enters the percent moisture in the numeric field provided. For example, if the percent moisture for laboratory rat chow is reported as 3 percent, the number 3 is entered. The number 100 should be entered for drinking water studies. If the percent moisture is not report the application assumes 5%.

### **Is the Body Weight Reported?**

The User should review the study to determine if the test organism body weights are reported. If body weights are reported, the User selects "Yes" by checking the appropriate box. If body weights are not reported, the User selects "No" by checking the appropriate box.

### **Body Weight with Units**

If body weight data are reported in the study, the User needs to select the appropriate value used by the application to calculate either a NOAEL or LOAEL dose. The User should select the body weight reported for the appropriate NOAEL or LOAEL exposure level group. The highest body weight should be used if both NOAEL and LOAEL exposure level groups are identified. The body weight is entered in the numeric field provided. Next, the User selects the appropriate units associated with the reported body weight from the pull down list. The list of available units is provided in Table 18.

<b>Table 18. Body Weight Units and Conversions</b>		
<b>Body Weight Fields</b>		<b>Conversion to BW in kg</b>
ng bw	nanograms body weight	multiply by 0.000000000001
ug bw	micrograms body weight	multiply by 0.000000001
mg bw	milligrams body weight	multiply by 0.000001
g bw	grams body weight	multiply by 0.001
kg bw	kilograms body weight	none
lb bw	pounds body weight	multiply by 0.4535924

If body weight data are not reported in the study, the User is required to select an appropriate default body weight. Table 19 provides a summary of default body weight values that are organism-, sex- and age-specific. The User selects the appropriate default body weight and enters the result in the numeric field provided. Default body weight units are reported in kilograms (kg). If a body weight value is not available in Table 19, the User may enter an appropriate value identified from another source. If an alternate value is entered, the User should enter the value in units of kg and provide a description of the value and reference in the comment field.

### **Body Weight Comments**

In the comment field provided for the body weights, the User enters information specific to any of the following:

- 1) A description of the body weight selected or calculated from the study for entry. The description should include the rationale for selection, any calculations and appropriate references to study table, figure and page numbers.
- 2) A description of any value selected from the default table and rationale.
- 3) A description of any alternative value selected from additional sources and the appropriate reference.

<b>Table 19. Default Body Weights</b>					
<b>General Organism Type</b>	<b>Specific Organism Type</b>	<b>Sex</b>	<b>Age</b>	<b>Default BW (kg)</b>	<b>Reference</b>
Mouse	BAF1	M	weaning to 90 days	0.0223	USEPA, 1987
Mouse	BAF1	M	90 days to 1 year	0.0261	USEPA, 1987
Mouse	BAF1	M	1 year or older	0.035	USEPA, 1987
Mouse	BAF1	F	weaning to 90 days	0.0204	USEPA, 1987
Mouse	BAF1	F	90 days to 1 year	0.0222	USEPA, 1987
Mouse	BAF1	F	1 year or older	0.03	USEPA, 1987
Mouse	B6C3F1	M	weaning to 90 days	0.0316	USEPA, 1987
Mouse	B6C3F1	M	90 days to 1 year	0.0373	USEPA, 1987
Mouse	B6C3F1	M	1 year or older	0.04	USEPA, 1987
Mouse	B6C3F1	F	weaning to 90 days	0.0246	USEPA, 1987
Mouse	B6C3F1	F	90 days to 1 year	0.0353	USEPA, 1987
Mouse	B6C3F1	F	1 year or older	0.035	USEPA, 1987
Mouse	unspecified	M	weaning to 90 days	0.02695	USEPA, 1987
Mouse	unspecified	M	90 days to 1 year	0.0317	USEPA, 1987
Mouse	unspecified	M	1 year or older	0.0375	USEPA, 1987
Mouse	unspecified	F	weaning to 90 days	0.0225	USEPA, 1987

Table 19. Default Body Weights					
General Organism Type	Specific Organism Type	Sex	Age	Default BW (kg)	Reference
Mouse	unspecified	F	90 days to 1 year	0.02875	USEPA, 1987
Mouse	unspecified	F	1 year or older	0.0325	USEPA, 1987
Rat	Fischer 344	M	weaning to 90 days	0.18	USEPA, 1987
Rat	Fischer 344	M	90 days to 1 year	0.38	USEPA, 1987
Rat	Fischer 344	M	1 year or older	0.4	USEPA, 1987
Rat	Fischer 344	F	weaning to 90 days	0.124	USEPA, 1987
Rat	Fischer 344	F	90 days to 1 year	0.229	USEPA, 1987
Rat	Fischer 344	F	1 year or older	0.25	USEPA, 1987
Rat	Long-Evans	M	weaning to 90 days	0.248	USEPA, 1987
Rat	Long-Evans	M	90 days to 1 year	0.472	USEPA, 1987
Rat	Long-Evans	M	1 year or older	0.5	USEPA, 1987
Rat	Long-Evans	F	weaning to 90 days	0.179	USEPA, 1987
Rat	Long-Evans	F	90 days to 1 year	0.344	USEPA, 1987
Rat	Long-Evans	F	1 year or older	0.35	USEPA, 1987
Rat	Osborne-Mendel	M	weaning to 90 days	0.263	USEPA, 1987
Rat	Osborne-Mendel	M	90 days to 1 year	0.514	USEPA, 1987
Rat	Osborne-Mendel	M	1 year or older	0.55	USEPA, 1987
Rat	Osborne-Mendel	F	weaning to 90 days	0.201	USEPA, 1987
Rat	Osborne-Mendel	F	90 days to 1 year	0.389	USEPA, 1987
Rat	Osborne-Mendel	F	1 year or older	0.4	USEPA, 1987
Rat	Sprague-Dawley	M	weaning to 90 days	0.267	USEPA, 1987
Rat	Sprague-Dawley	M	90 days to 1 year	0.523	USEPA, 1987
Rat	Sprague-Dawley	M	1 year or older	0.6	USEPA, 1987
Rat	Sprague-Dawley	F	weaning to 90 days	0.204	USEPA, 1987
Rat	Sprague-Dawley	F	90 days to 1 year	0.338	USEPA, 1987
Rat	Sprague-Dawley	F	1 year or older	0.35	USEPA, 1987
Rat	Wistar	M	weaning to 90 days	0.217	USEPA, 1987
Rat	Wistar	M	90 days to 1 year	0.462	USEPA, 1987
Rat	Wistar	M	1 year or older	0.5	USEPA, 1987
Rat	Wistar	F	weaning to 90 days	0.156	USEPA, 1987
Rat	Wistar	F	90 days to 1 year	0.297	USEPA, 1987
Rat	Wistar	F	1 year or older	0.32	USEPA, 1987
Rat	unspecified	M	weaning to 90 days	0.235	USEPA, 1987
Rat	unspecified	M	90 days to 1 year	0.4702	USEPA, 1987
Rat	unspecified	M	1 year or older	0.51	USEPA, 1987
Rat	unspecified	F	weaning to 90 days	0.2024	USEPA, 1987
Rat	unspecified	F	90 days to 1 year	0.3846	USEPA, 1987
Rat	unspecified	F	1 year or older	0.4	USEPA, 1987
guinea pig	unspecified	M	weaning to 90 days	0.48	USEPA, 1987

Table 19. Default Body Weights					
General Organism Type	Specific Organism Type	Sex	Age	Default BW (kg)	Reference
guinea pig	unspecified	M	90 days to 1 year	0.89	USEPA, 1987
guinea pig	unspecified	M	1 year or older	1	USEPA, 1987
guinea pig	unspecified	F	weaning to 90 days	0.39	USEPA, 1987
guinea pig	unspecified	F	90 days to 1 year	0.86	USEPA, 1987
guinea pig	unspecified	F	1 year or older	0.9	USEPA, 1987
hamster	golden Syrian	M	weaning to 90 days	0.097	USEPA, 1987
hamster	golden Syrian	M	90 days to 1 year	0.134	USEPA, 1987
hamster	golden Syrian	M	1 year or older	0.15	USEPA, 1987
hamster	golden Syrian	F	weaning to 90 days	0.095	USEPA, 1987
hamster	golden Syrian	F	90 days to 1 year	0.145	USEPA, 1987
hamster	golden Syrian	F	1 year or older	0.16	USEPA, 1987
hamster	Chinese & Djungarain	M	weaning to 90 days	0.03	USEPA, 1987
hamster	Chinese & Djungarain	M	90 days to 1 year	0.041	USEPA, 1987
hamster	Chinese & Djungarain	M	1 year or older	0.04	USEPA, 1987
hamster	Chinese & Djungarain	F	weaning to 90 days	0.025	USEPA, 1987
hamster	Chinese & Djungarain	F	90 days to 1 year	0.038	USEPA, 1987
hamster	Chinese & Djungarain	F	1 year or older	0.035	USEPA, 1987
hamster	unspecified	M	weaning to 90 days	0.0635	USEPA, 1987
hamster	unspecified	M	90 days to 1 year	0.0875	USEPA, 1987
hamster	unspecified	M	1 year or older	0.095	USEPA, 1987
hamster	unspecified	F	weaning to 90 days	0.2425	USEPA, 1987
hamster	unspecified	F	90 days to 1 year	0.5025	USEPA, 1987
hamster	unspecified	F	1 year or older	1.03	USEPA, 1987
gerbil	unspecified	M	weaning to 90 days	0.048	USEPA, 1987
gerbil	unspecified	M	90 days to 1 year	0.084	USEPA, 1987
gerbil	unspecified	M	1 year or older	0.1	USEPA, 1987
gerbil	unspecified	F	weaning to 90 days	0.04	USEPA, 1987
gerbil	unspecified	F	90 days to 1 year	0.073	USEPA, 1987
gerbil	unspecified	F	1 year or older	0.09	USEPA, 1987
cat	unspecified	M	weaning to 90 days	1.72	USEPA, 1987
cat	unspecified	M	90 days to 1 year	3.66	USEPA, 1987
cat	unspecified	M	1 year or older	4	USEPA, 1987
cat	unspecified	F	weaning to 90 days	1.49	USEPA, 1987
cat	unspecified	F	90 days to 1 year	2.96	USEPA, 1987
cat	unspecified	F	1 year or older	3.1	USEPA, 1987
dog	unspecified	M	weaning to 90 days	2.4	USEPA, 1987
dog	unspecified	M	90 days to 1 year	10.8	USEPA, 1987
dog	unspecified	M	1 year or older	14	USEPA, 1987
dog	unspecified	F	weaning to 90 days	1.97	USEPA, 1987

Table 19. Default Body Weights					
General Organism Type	Specific Organism Type	Sex	Age	Default BW (kg)	Reference
dog	unspecified	F	90 days to 1 year	10.1	USEPA, 1987
dog	unspecified	F	1 year or older	14	USEPA, 1987
rabbit	unspecified	M	weaning to 90 days	2.86	USEPA, 1987
rabbit	unspecified	M	90 days to 1 year	3.76	USEPA, 1987
rabbit	unspecified	M	1 year or older	4	USEPA, 1987
rabbit	unspecified	F	weaning to 90 days	3.1	USEPA, 1987
rabbit	unspecified	F	90 days to 1 year	3.93	USEPA, 1987
rabbit	unspecified	F	1 year or older	4.1	USEPA, 1987
chicken	unspecified	M	all ages	1.3	USEPA, 1987
chicken	unspecified	F	all ages	1.6	USEPA, 1987
chicken	domestic	BH	chicks		
pig	domestic	M	all ages	225	USEPA, 1987
pig	domestic	F	all ages	225	USEPA, 1987
pig	miniature	M	all ages	72.5	USEPA, 1987
pig	miniature	F	all ages	72.5	USEPA, 1987
mink	unspecified	M	all ages	1.7	USEPA, 1987
mink	unspecified	F	all ages	1	USEPA, 1987
Mallard	mallard	F	Adult	1.1	USEPA, 1993
Mallard	mallard	M	Adult	1.2	USEPA, 1993
Mallard	mallard	JV	10 days	0.092	USEPA, 1993
Mallard	mallard	JV	30 days	0.46	USEPA, 1993
Quail	Japanese	F	Adult	0.1	Dunning, 1993
Quail	Japanese	M	Adult	0.09	Dunning, 1993
Quail	bobwhite	F	Adult	0.17	USEPA, 1993
Quail	bobwhite	M	Adult	0.16	USEPA, 1993
Quail	bobwhite	JV	10 days	0.012	USEPA, 1993
Quail	bobwhite	JV	30 days	0.04	USEPA, 1993
Pheasant	ring-necked	F	Adult	0.95	Dunning, 1993
Pheasant	ring-necked	M	Adult	1.3	Dunning, 1993
Shrew	short-tailed	M	Adult	0.017	USEPA, 1993
Shrew	short-tailed	F	Adult	0.017	USEPA, 1993
Mouse	deer mouse	M	Adult	0.02	USEPA, 1993
Mouse	deer mouse	F	Adult	0.019	USEPA, 1993
Vole	prairie vole	BH	Adult	0.042	USEPA, 1993
Vole	meadow vole	M	Adult	0.043	USEPA, 1993
Vole	meadow vole	F	Adult	0.039	USEPA, 1993

## **Is the Intake Rate Reported?**

If intake rates are reported, the User selects "Yes" by checking the appropriate box. If intake rates are not reported, the User selects "No" by checking the appropriate box. In gavage or other oral exposures (capsule), the User selects "Yes" by checking the appropriate box.

## **Intake Rate with Units**

If the intake rate is reported in the study, the User needs to select the appropriate value to be used by the application to calculate either a NOAEL or LOAEL dose. The User should select the body weight reported for the appropriate NOAEL or LOAEL exposure level group. The highest intake rate should be used if both NOAEL and LOAEL exposure level groups are identified. The intake rate is entered in the numeric field provided. It is assumed by the application that the intake rate entered (for dietary studies) is dry weight-based. If the User gathers information from the study that reports otherwise, then the User should convert the intake rate to a dry weight basis and report in detail the necessary conversion in the Intake Rate Comment Field.

Next the User selects the appropriate units associated with the intake rate from the pull down list. The list of intake rate units is provided in Table 20. In instances where the intake rate is not reported, the application calculates the intake rate automatically using allometric equations based on the body weight, specific class and exposure route for the test organism. The intake rate is calculated and reported in the Score Information Screen in units of kg dw per day or L per day (see Appendix A).

<b>Table 20. Intake Rate Units and Conversions</b>		
<b>Intake Rate Fields</b>		<b>Conversion to kg/day or L/day</b>
kg/d (or L/d)	kilograms or liters per day	multiply by 1
kg/kg BW/day	kilograms or liters per kilogram BW per day	multiply by BW in kg
kg/org/d or	kilograms or liters per organism per day	multiply by BW in kg
g/d or ml/day	grams per day	multiply by 0.001
g/kg BW/d or	grams per kilogram BW per day	multiply by 0.001 then multiply by BW in kg
g/org/d or	grams per organism per day	multiply by 0.001 then multiply by BW in kg
mg/d or ul/d	milligrams per day	multiply by 0.000001
mg/kg BW/d or	milligrams per kilogram BWper day	multiply by 0.000001 then multiply by BW in kg
mg/org/d or	milligrams per organism per day	multiply by 0.000001 then multiply by BW in kg
ug/d	micrograms per day	multiply by 0.000000001
ug/kg bw/d	micrograms per kilogram BWper day	multiply by 0.000000001 then multiply by BW in
ug/org/d	micrograms per organism per day	multiply by 0.000000001 then multiply by BW in
ng/d	nanograms per day	multiply by 0.000000000001
ng/kg bw/d	nanograms per kilogram BWper day	multiply by 0.000000000001 then multiply by
ng/org/d	nanograms per organism per day	multiply by 0.000000000001 then multiply by

## **Intake Rate Comments**

In the comment field provided for the body weights, the User enters information specific to any of the following:

- A description of the intake rate selected or calculated from the study for entry. The description should include the rationale for selection, any calculations and appropriate references to study table, figure and page numbers.
- A description of any value selected from the default table and rationale.
- A description of any alternative value selected from additional sources and the appropriate reference.

## **Results for the NOAEL**

Within these fields, the User enters information concerning the experimental results for the NOAEL exposure (dose) level. The User enters information here in instances where ONLY A NOAEL is reported and no LOAEL is reported. In these instances, it is important to evaluate the study design to assess the power of observing an effect, if it were present. Statistical power is based upon the number of test organisms, the endpoint effect level, and the error associated with the endpoint effect level measurement. If the distribution of values in the control group and the exposed group are both approximately normal, and if the number of animals in the control and the exposed group are similar, then power of the NOAEL value can be estimated from the information entered below. The numeric fields provided cannot be blank. If any fields are blank (due to missing information), the study power is not calculated and the application reports “not calculated”. A detailed description of the power calculation is provided as Appendix B.

**Number of Exposed Organisms.** The User enters the total number of organisms exposed in the numeric field provided. If the total number of exposed organisms is not reported, the User leaves the numeric field blank. A blank field is evaluated as null and power is not calculated.

**Number of Control Organisms.** The User enters the total number of control organisms from the dose level group of the NOAEL in the numeric field provided. If the total number of control organisms is not reported, the field is left blank. The blank field is evaluated as null and power is not calculated by the application.

**Mean of Endpoint in Exposed Organisms.** The User enters the mean of the NOAEL result for the exposed organisms in the numeric field provided. If the mean of the endpoint of concern is not provided, the field is left blank. A blank field is evaluated as null and power is not calculated.



**Mean of Endpoint in Control Organisms.** The User enters the mean of the selected endpoint for the control organisms in the numeric field provided. If the mean of the endpoint of concern is not provided, the field is left blank. A blank field is evaluated by the system as null and power is not calculated.

**Standard Deviation of Endpoint in Exposed Organisms.** The User enters the standard deviation of the endpoint mean from the exposed organisms in the numeric field provided. If the standard deviation of the endpoint of concern is not provided, the field is left blank. The blank field is evaluated as null and power is not calculated.

If standard error is reported instead of the standard deviation then the standard deviation can be calculated using the standard error and the sample size as  $StDev = StError * \text{square root of } N$ .

**Standard Deviation of Endpoint in Control Organisms.** The User enters the standard deviation of the endpoint mean from the control organisms in the numeric field provided. If the standard deviation of the endpoint of concern is not provided, the field is left blank. A blank field is evaluated as null and power is not calculated. If only the standard error is reported, the User is instructed to approximate the standard deviation by taking the square root of the standard error.

If standard error is reported instead of the standard deviation then the standard deviation can be calculated using the standard error and the sample size as  $StDev = StError * \text{square root of } N$ .

**Confidence Alpha.** The User enters the desired statistical power. For the purposes of deriving wildlife TRVs to derive an Eco-SSL, the study should have the statistical power to detect at least a 95 percent chance of seeing an effect if it is present. This 95 percent chance is reported as the confidence alpha and is equal to  $1.00 - (95/100)$ , or 0.05. For a standard normal curve, a confidence alpha of 0.05 is equal to a Z value of 1.645. This Z value is the critical value to which the calculated study power is compared. The User selects the desired confidence alpha (0.05) from the pull down list provided.

At this point in the data entry process, the "Endpoint Information" screen is now complete. The User verifies that all data entered are correct and clicks on the "Next" button at the bottom of the screen to continue. The User should not use the back arrow to return to a previous data entry screen to correct errors, as deletion of data results.

#### **4.5 Data Evaluation Score**

For the convenience of the User, the Data Evaluation screen provides a summary of the information required to determine a data evaluation score for each endpoint entered. This summary is provided at

the top of the Score Information screen. The Data Evaluation Scoring system is described in SOP #3 (Appendix 4-4).

For this summary screen, the data presented for several fields are converted to the appropriate units that are used to calculate a final NOAEL and/or LOAEL value. These fields include body weight, intake rate, and the NOAEL and/or LOAEL. Each of these conversions are described in detail below:

- **Body Weight.** The application converts reported body weights to units of kilograms. The equations are used to convert reported body weight units to kilograms and are presented in Table 17a. The application automatically converts the entered body weight to units of kilograms based on the units entered by the User.
- **Intake Rate.** The application converts the reported intake rate to units of kilograms of food per organism per day. The equations that are used to convert the reported intake rate units to kilograms of food per organism per day (dry weight) are presented in Table 20. If the intake rate is assigned by the application, based on the default allometric equations for food and water ingestion, no conversion is required as the equations estimate intake based on the appropriate units.
- **Conversion to Dose.** The application converts the entered NOAEL and/or LOAEL concentration or dose values to the appropriate units of mg of contaminant per kg BW per day. The equations used for these conversions are provided in Table 8. If the NOAEL and/or LOAEL concentrations are expressed on a wet weight basis in the study, then the application makes the appropriate conversion to dry weight based on the moisture content entered by the User.

The final data evaluation score assigned to the NOAEL and/or LOAEL is based on the addition of individual scores for ten study attributes. These ten attribute scores are described in the following subsection and are summarized in Table 21. For each attribute, a score is assigned ranging from 0 (no merit is establishing a TRV) to 10 (extremely valuable and relevant to establishing a TRV). It is important to note that a low score does not imply that the study is poor, only that it is not optimal for developing a TRV. For each of the study attributes, the User selects the appropriate score from the pull down lists provided. The application defaults to the appropriate score based on the information entered. The User can, however, alter the default scores under special circumstances. If any of the individual attribute scores are equal to 0 the total score is equal to 0 and the study is not used for the derivation of Wildlife TRVs.

Table 21. Summary of Data Evaluation Scoring System		
Attribute	Description	Score
Data source	Primary	10
	Secondary	0

Table 21. Summary of Data Evaluation Scoring System		
Attribute	Description	Score
Dose Route	Dietary	10
	Other oral (gavage, capsule)	8
	Other oral (liquid)	5
	Not oral or water (inhalation, intravenous, subcutaneous, dermal, etc.)	0
Test Substrate	Test substance concentrations reported as actual measured values	10
	Test substance concentrations reported as nominal values	5
	Test substance concentrations calculated	1
	Test substance concentrations not reported	0
Contaminant Form	Contaminant form is known and is the same or similar to the of medium of concern	10
	Contaminant form is irrelevant to absorption or biological activity	10
	Contaminant form is known and is different from that found in the medium of concern	5
	Contaminant form is not reported	4
Dose Quantification	Administered doses reported as mg/kg-BW	10
	Administered doses need to be calculated and intake rates and body weights provided	7
	Administered doses need to be calculated and only one value (intake or body weight) provided	6
	Administered doses need to be calculated based on estimated intake rates and body weights	5
	Administered doses cannot be calculated from the information provided	0
Endpoint	Reported endpoint is a reproductive effect	10
	Reported endpoint is lethality (chronic or subchronic exposures)	9
	Reported endpoint is reduction in growth	8
	Reported endpoint is sublethal change in organ function, behavior or neurological function	4
	Reported endpoint is a biomarker of exposure with unknown relationship to fitness	1
Dose Range	Both a NOAEL and a LOAEL are identified; values are within a factor of 3	10
	Both a NOAEL and a LOAEL are identified; values are within a factor of 10	8
	Both a NOAEL and a LOAEL are identified; values are not within a factor of 10	6
	Only a NOAEL or a LOAEL is identified	4
	Study lacks a suitable control group	0
Statistical Power	At least 90% chance of seeing a difference that is biologically significant	10
	NOAEL and LOAEL available or LOAEL only available	10
	At least 75% chance of seeing a difference that is biologically significant	8
	At least 50% chance of seeing a difference that is biologically significant	6
	Less than a 50% chance of detecting a difference that is biologically significant	3
Exposure Duration	Power of NOAEL cannot be determined	1
	Exposure duration encompasses multiple generations of test species	10
	Exposure duration is at least 0.1 times the expected life span of the test species or occurs during a critical life phase	10
	Exposure duration is shorter than 0.1 times the expected life span of the test species but multiple dosing intervals occur	6
	Exposure duration is shorter than 0.1 times the expected life span of the test species and only a single dose exposure occurs.	3
Test Conditions	Exposure duration is acute	0
	Follows standard guidelines and reports all measurement parameters	10
	Does not follow a standard guideline, but does report all testparameters	10
	Follows a standard guideline but does not report test parameters	7
	Does not follow a standard guideline and reports some, but not all of the test parameters do not report any test parameters	4
		2

### **Data Source Score**

All studies considered for TRV derivation are from primary sources. Secondary sources of data are not used to derive an Eco-SSL. The application automatically assigns a Source score based on the Primary Source entry. If the "No" box is selected, the application exits completely from the program. Since the User has progressed to this point of the data entry process, the application assumes that the study is a primary source and a score of 10 is assigned.

### **Dose Route Score**

The Eco-SSLs reflect the concentrations of contaminants in soil protective of oral exposure via ingestion of soil or food items. Therefore, toxicological studies that use oral exposure (food, water, gavage, or capsule) are considered to be relevant compared to studies that use other non-oral methods of administration (inhalation, interperitoneal injections, dermal, intravenous, subcutaneous). Studies that report results for non-oral exposures are not used to establish TRVs and should be labeled as “non oral” using the literature rejection criteria discussed in Section 2.0.

Dietary studies are preferred to other oral exposures via gavage or capsule. Gavage and capsule studies do not generally reflect natural feeding behaviors and the solute carrier used to deliver the gavage dose can alter the kinetics of the tissue dose.

The application automatically assigns a Dose Route score based upon the Exposure Type and Route of Exposure information previously entered by the User. If the Route of Exposure is via food (FD), a score of 10 is assigned. If the route of exposure is via other oral routes (OR) or gavage (GV), a score of 8 is assigned. If the route of exposure is via drinking water (DW), a score of 5 is assigned. If the route of exposure is a choice between media (CH), a score of 0 is assigned. If the route of exposure is not reported (NR), a score of 0 is assigned.

### **Test Substrate Score**

Studies that report contaminant exposure concentrations or doses in the diet or drinking water confirmed by analytical measurement - “measured”- are preferred compared to those that do not measure or verify the exposure doses or concentrations.

The application automatically assigns a Test Substance score based on the value the User entered under “Method of Contaminant Analysis”. If the method of contaminant analysis is measured (M), a score of 10 is assigned. If unmeasured (U) is entered, a score of 5 is assigned. If calculated (C) is entered, a score of 1 is assigned.

### **Contaminant Form Score**

The wildlife TRVs are expressed in units of ingested dose (mg/kg BW/day or mg/L/day). Expression as units of ingested dose implicitly assumes that absorption of the contaminant from the test medium is the same as for the site medium. This assumption may be reasonable when the two media are the same (e.g., both water, both similar food items), but may not be true if the two media are different (e.g., test medium = water, site medium = soil). To account for the potential difference in absorption between different media, it is necessary to convert both the ingested dose and the TRV to units of absorbed dose:

$$\text{Site Dose (absorbed)} = \text{Site Dose (ingested)} * \text{Absorption fraction from site medium}$$

$$\text{TRV(absorbed dose)} = \text{TRV(ingested dose)} * \text{Absorption fraction in test medium}$$

Studies reporting oral absorption fraction from the test medium are preferred to those where the absorption fraction is unknown. The assumption of equal absorption of the contaminant from the test and site medium is also reasonable when the form of the contaminant is the same in the test medium versus the site medium. Some contaminants are better absorbed and more biologically active than others. The best known examples are differences between inorganic and organic mercury, and inorganic and organic arsenic. Preferred studies use the same form of a contaminant in the exposure medium compared to that found typically on a waste site.

The User assigns a Contaminant Form score based upon the similarity of the contaminant form used in the study to contaminant forms found in environmental media. A summary of common contaminant forms found in environmental media is provided as Table 22. If the contaminant form used in the study is the same or similar to that in environmental media, a score of 10 is selected by the User. If the contaminant form is not relevant to absorption or biological activity, a score of 10 is selected. If the contaminant form is different from that in environmental media, a score of 5 is selected. If the contaminant form is not reported (NR), a score of 4 is selected by the User.

[Insert Table 22]

### **Dose Quantification Score**

Some toxicological studies report contaminant exposures in terms of dose (mg of contaminant per unit of body weight), but some only report the concentration of the contaminant in the exposure vehicle (food or drinking water). In these cases, it is necessary to convert the concentrations to a dose using an intake rate (food or water) and a body weight. Studies that report results as doses are preferred over those that report concentrations and the application automatically assigns these studies a Dose Quantification Score of 10. Studies that report exposures as concentrations are scored in the following manner according to preference:

- If both body weight and intake rates are reported for the test organisms in the study (the User is prompted to enter this information earlier in the data entry process), then the study endpoint receives a score of 7. The application automatically uses the body weight and intake rate values entered previously to convert the exposure concentrations to doses.
- If only one value (intake rate or body weight) is provided for the test organisms, a score of 6 is assigned.
- If the study does not report either body weights or intake rates for the test organism, the application assigns a score of 5. Doses are automatically calculated based on the default body weight and intake rate values previously entered by the User.
- If the administered doses cannot be calculated from the information provided, a score of 0 is assigned by the User from the pull down menu.

If the study uses an exposure method of gavage, capsule or other oral exposure where the administered amount is known, then the dose quantification score should be entered as follows by the User. The User is required to select these values from the pull down list provided:

- If the body weight is reported in the study (this is the only parameter required to convert from amount administered to dose), then the study endpoint is assigned a score of 7.
- If the body weight is not reported and the value needs to be estimated based on a default, then the study is assigned a score of 5.

### **Endpoint Score**

In most ecological risk assessments, assessment endpoints focus on the effects of long term exposures of contaminants on population sustainability. The specific toxicological endpoints used as measurements of population sustainability in ERAs are site-specific. For the purposes of identification and derivation of a TRV for calculation of an Eco-SSL, the endpoints are predefined. The following endpoints are selected in order of preference for derivation of TRVs.

- Studies measuring reproductive endpoints are considered the most appropriate and are preferred. Reproductive endpoints are assigned a score of 10. Within the coding system, this includes any endpoint within the reproduction (REP) effect group (Table 16).
- Studies measuring mortality or survival (chronic) as an endpoint are also considered appropriate but are less preferable to reproductive endpoints. These study endpoints

are assigned a score of 9. Within the coding system, this includes any endpoint within the mortality (MOR) effect group (Table 16).

- Studies measuring growth are also considered appropriate for establishing TRVs. These study endpoints are assigned a score of 8. Within the coding system, this includes any endpoint within the (GRO) effect group (Table 16).
- Studies measuring organ function, behavior or neurological function are considered less useful in establishing TRVs. These study endpoints are assigned a score of 4. Within the coding system, this includes any endpoint within the pathology (PTH), behavior (BEH) or physiology (PHY) effect groups. The User may elect to score such studies lower if it is decided that the effect does not have an adverse effect on organism “fitness” or health (Table 16).
- Studies measuring biochemical effects and changes either hormonal, chemical or enzymatic are considered the least useful in establishing TRVs. These study endpoints are assigned a score of 1. Within the coding system, this includes any endpoint within the biochemical (BIO) effect group. The User may elect to score such study measures higher if it is decided that the measure can be related to organism “fitness” or health. Biomarkers of exposure should always be scored as a 1.

### **Dose Range Score**

The TRV represents a threshold on the dose-response curve between the absence and presence of the adverse effect of concern. Establishing this threshold involves identification of two values from the toxicological study, a no observed adverse effect level (NOAEL) and a lowest observed adverse effect level (LOAEL). The NOAEL is defined as the lowest administered dose that does not cause a significant adverse effect. The LOAEL is defined as the lowest administered dose that causes a significant adverse effect. Experimentally, the threshold value is estimated by assuming it lies between the NOAEL and the LOAEL. Therefore, a study using a series of doses spanning the threshold identifying both a NOAEL and a LOAEL is more valuable than a study that identifies only a NOAEL or LOAEL. Typically these studies use only one dose, or multiple doses that do not bracket the threshold.

The application automatically assigns a Dose Range score based upon the NOAEL and/or LOAEL values entered previously by the User. These selection is the one that appears in the pull down menu on the score sheet. The User, however, may select a different result from the choices provided.

If both a NOAEL and a LOAEL are identified and the values are within a factor of 3, a score of 10 is assigned. If both a NOAEL and a LOAEL are identified and the values are within a factor of 10, a score of 8 is assigned. If both a NOAEL and a LOAEL are identified, but the values are not within a factor of 10, a score of 6 is assigned. If only a NOAEL or a LOAEL is identified, a score of 4 is

assigned. If the study lacks a suitable control group, a score of 0 is assigned by the User. Unsuitable control groups include: Historical (H), No Methodology (K), Positive (P), and Carrier or Solvent (V). If the control type is not reported (NR), a score of 0 is assigned.

### **Power Score**

A NOAEL is defined as the highest dose that does not cause a significant effect in the selected endpoint compared to the control. However, the ability to detect an effect (i.e., the reliability of the NOAEL) depends on a number of factors, of which the most important are:

- 1) the variability of the measurement endpoint in both the control and the dosed groups
- 2) the number of animals in each group

That is, as variability in the measurement endpoint goes up and the number of experimental animals goes down, the ability to detect an effect becomes very poor, and a dose which really does cause an effect may be incorrectly identified as a NOAEL.

There are a number of standard statistical procedures available for calculating the statistical power of a study to detect an effect which can be used to evaluate the reliability of NOAEL values. The statistical power test used for the toxicological Data Evaluation process for establishing wildlife TRVs is described in Appendix B.

If both a NOAEL and a LOAEL are reported or if only a LOAEL is reported, the power calculation is not applicable and a score of 10 is assigned by the application. If only a NOAEL is reported and the calculated power is greater than or equal to 95 percent, a score of 10 is assigned. If only a NOAEL is reported and the calculated power is greater than or equal to 75 percent, a score of 8 is assigned. If only a NOAEL is reported and the calculated power is greater than or equal to 50 percent, a score of 6 is assigned. If only a NOAEL is reported and the calculated power is less than 50 percent, a score of 3 is assigned. If only a NOAEL is reported but the power cannot be calculated because one or more of the required fields is null, a score of 1 is assigned.

### **Exposure Duration Score**

The usefulness of a study result for derivation of a TRV is partially dependent on the duration of the exposure. Chronic and multiple generation exposures are preferred to subchronic or acute exposures. Chronic exposures are generally more representative of the type of exposure which may occur at a contaminated site.

The User assigns an Exposure Duration score based upon the duration of the study exposure and the lifespan of the test organism. A summary of typical laboratory test organism lifespans is provided in



Table 23. To assess if the exposure duration is representative of the expected lifespan, the User multiplies the test organism lifespan by 0.1. For example, if the test organism is a gerbil with an assumed lifespan of 2.5 years ( $2.5 \text{ years} \times 0.1 = 0.25 \text{ years}$  or 12 weeks), an exposure duration of 9 weeks is less than 0.1 times the expected lifespan. If the duration of the study exposure encompasses multiple generations of the test organism, a score of 10 is selected. If the duration of exposure is at least 0.1 times the expected lifespan of the test organism or occurs during a critical lifestage, a score of 10 is selected. If the duration of exposure is less than 0.1 times the expected lifespan of the test organism and multiple dosing intervals occur, a score of 6 is selected. If the duration of exposure is less than 0.1 times the expected lifespan and only a single dose exposure occurs, a score of 3 is assigned. If the exposure duration is acute (a single oral dose), a score of 0 is selected.

<b>Table 23. Default Species Lifespan</b>				
<b>Weaning, Puberty and Lifespan</b>				
<b>Group</b>	<b>Species</b>	<b>Weaning (days)</b>	<b>Puberty (days)</b>	<b>Lifespan (years)</b>
<b>Laboratory Rodents</b>				
	Mice	21	50	2*
	Rats	21	56	2*
	Guinea Pigs	14	70	6
	Hamsters	21	60	2.5
	Gerbils	21	70	3
<b>Other Laboratory Mammals</b>				
	Cats	49	240	15
	Dogs, Beagles	42	240	15
	Rabbits, New Zealand	56	190	6
<b>Other Animals</b>				
	Chicken	NA	NA	24
	Pig	NR	150	27
	Mink	56	300	NR
	Pheasant			
	Mallard			
	Vole			
	Shrew			
	Dove			
	Quail			
<b>Source:</b> USEPA, 1987 Table 1-1 (EPA/600/6-87/008) * Substantial strain variability NA = Not Applicable NR = Not Reported				

### **Test Condition Score**

The User is prompted earlier in the data entry process to identify if the study follows a standard guideline for toxicity testing and if not how many of the parameters the study reports. The standard guidelines and test parameters are provided in Table 12. If the study follows a standard guideline and reports all measurement parameters, then a score of 10 is assigned. If the study does not follow standard guidelines but reports all parameters, a score of 10 is also assigned. If the study follows a standard guideline but does not report all test parameters, then a score of 7 is assigned. If the study does not follow a standard guideline, but reports some but not all of the test parameters, then a score of 4 is assigned. If the study does not report any parameters, a score of 2 is assigned.

### **Final Total Score**

The "Score Information" screen is now complete. The User verifies that all data entered are correct and clicks on the "Calculate Score" button at the bottom of the screen to calculate the final total score. The User should not use the back arrow to return to a previous data entry screen to correct errors, this action results in a duplication of information.

The total score is based upon the evaluation of each of the ten attribute scores identified above. The total score is calculated for a specific endpoint by taking the sum of all ten study attribute scores (a "perfect" study is given a score of 100). However, if any one study attribute is given a score of 0, the final score is also be set to equal 0. This ensures minimum standards for study results that are used to derive wildlife TRVs. Studies without appropriate controls, of acute exposure duration, without reported test substance concentrations and non-oral exposures are excluded from the TRV derivation process.

Several scoring examples are provided below:

### **Lowest Possible Total Score (all attribute scores are the minimum score without defaulting to 0:**

<b>Study Attribute</b>	<b>Score</b>
Source Score:	10
Dose Route Score:	5
Test Substrate Score:	1
Contaminant Form Score:	4
Dose Quantification Score:	5
Endpoint Score:	1
Dose Range Score:	4
Power Score:	1

Exposure Duration Score:	3
Test Parameter Score:	2
<b>Total Score</b>	<b>36</b>

**Case Where Individual Attribute Score = 0**

<b>Study Attribute</b>	<b>Score</b>
Source Score:	10
Dose Route Score:	5
Test Substrate Score:	1
Contaminant Form Score:	4
Dose Quantification Score:	0
Endpoint Score:	1
Dose Range Score:	4
Power Score:	1
Exposure Duration Score:	3
Test Parameter Score:	2
<b>Total Score</b>	<b>0</b>

Final Score set to zero, due to Dose Quantification Score

**Highest Possible Total Score available (all attribute scores are the maximum score):**

<b>Study Attribute</b>	<b>Score</b>
Source Score:	10
Dose Route Score:	10
Test Substrate Score:	10
Contaminant Form Score:	10
Dose Quantification Score:	10
Endpoint Score:	10
Dose Range Score:	10
Power Score:	10
Exposure Duration Score:	10
Test Parameter Score:	10
<b>Total Score</b>	<b>100</b>

At this point of the data entry process, the User completes data entry and scoring for the selected endpoint and clicks on "Finish this Endpoint" to proceed. The User should **not** use the back arrow to return to a previous data entry screen to correct errors as this would result in a duplication of information.

If there is another endpoint associated with the selected phase (the selected phase is provided in the navigation bar at the top of the screen), the User selects "Yes" when prompted for another endpoint and begins entry of that endpoint at the Endpoint Information screen. If there are no other endpoints associated with the selected phase, then the User selects "No".

## **5.0 DATA MODIFICATION**

Modifications are completed by the system administrator using a Microsoft Access driven interface.

## **6.0 REPORTS**

These options in the Web-based data entry system are not fully functional.

## APPENDIX A

### ALLOMETRIC EQUATIONS FOR DEFAULT INTAKE RATES

#### Food Ingestion Rates

Where food ingestion rates are not reported in the individual respective toxicological studies, the food ingestion rates are estimated using the allometric equations of Nagy (1987). Nagy (1987) derived equations to estimate dry-weight-based food ingestion rates for mammals and birds based on body mass. Food ingestion rates are derived using the following equations:

For mammals:

$$IR_{food} = 0.0687 \times BW^{0.822} \quad (1)$$

where:

$IR_{food}$  = Ingestion rate of food, wet weight basis (Kg/day);  
0.0687 = Mathematical constant derived by Nagy (1987);  
BW = Body weight of the ROI (Kg); and  
0.822 = Mathematical constant derived by Nagy (1987).

For birds:

$$IR_{food} = 0.0582 \times BW^{0.651} \quad (2)$$

where:

$IR_{food}$  = Ingestion rate of food, wet weight basis (Kg/day);  
0.0582 = Mathematical constant derived by Nagy (1987);  
BW = Body weight of the ROI (Kg);  
0.651 = Mathematical constant derived by Nagy (1987); and

#### Water Ingestion Rates

If the water ingestion rate for the test species is not reported in the respective toxicological study under review then the water ingestion rate for the test species is estimated used an allometric equation. For avian species, Calder and Braun (1983) developed an equation for estimation of drinking water ingestion ( $IR_{water}$ ) based on the body weight of the bird where:

$$IR_{water} = 0.059 \times BW^{0.67} \quad (3)$$

where:

$IR_{water}$  = Ingestion rate of water, (L/day);  
 0.059 = Mathematical constant derived by Calder and Braun (1983);  
 BW = Body weight of the test species (kg); and  
 0.67 = Mathematical constant derived by Calder and Braun (1983).

Calder and Braun (1983) also developed an allometric equation for drinking water ingestion by mammals.

$$IR_{water} = 0.099 \times BW^{0.90} \quad (4)$$

where:

$IR_{water}$  = Ingestion rate of water, (L/day);  
 0.099 = Mathematical constant derived by Calder and Braun (1983);  
 BW = Body weight of the test species (kg); and  
 0.90 = Mathematical constant derived by Calder and Braun (1983).

## APPENDIX B

### STATISTICAL POWER TEST

If the distributions of values in the control group and the exposed group are both approximately normal, and if the number of animals in the control and the exposed group are similar, then power of the NOAEL value can be estimated as follows.

First, calculate the value of  $Z_{\delta}$  from the following equation:

$$Z_b = 0.5 \left( \frac{\Delta}{s} \right) \sqrt{N} - Z_a$$

where:

- $Z_{\delta}$  = Value of Z needed to detect a difference of  $\Delta$  with confidence " and power  $\delta$  between the mean of two distributions each with standard deviation  $\sigma$
- $\Delta$  = Assumed difference between the exposed and control groups (i.e., the difference that is of concern to you as a biologically significant effect)
- $\bar{X}_c$  = Mean of the control group \* 0.2
- $\sigma$  = Pooled standard deviation of exposed and control groups. When the number of samples in each group is the same, this is simply the square root of the average of the squares of the standard deviation for each group:

$$s = \frac{[(N_1 - 1) * s_1^2] * [(N_2 - 1) * s_2^2]}{(N_1 + N_2 - 2)}$$

- $N$  = Number of animals in control plus exposed group combined
- $Z_{\alpha}$  = Value of Z when the area to the right of Z on the standard normal curve is equal to  $100*(1-\alpha)$ . For  $\alpha = 0.05$ , the value of  $Z_{\alpha}$  is 1.645.

Then, compare the calculated value of  $Z_{\delta}$  to a critical value selected from the table below:

<b>Power</b>	<b>Beta</b>	<b>Z<sub>b</sub> (Critical)</b>
25%	0.75	-0.319
50%	0.50	0.000
75%	0.25	0.319
80%	0.20	0.842
90%	0.10	1.283
95%	0.05	1.645

If the calculated value of  $Z_{\delta}$  is larger than the critical value, then the experimental data have the necessary power to detect a difference of concern ( ) in approximately  $100 \times (1 - \beta)\%$  of all tests. If the calculated value is less than the critical value, the power of the test is below the target.

For example, suppose that you are reviewing a study where the following results are presented:

<b>Parameter</b>	<b>Control</b>	<b>Exposed</b>
Dose	0	35
Study Mean	100	120
Study Stdev	30	30
N	8	8

Using a standard one-tailed t-test, the author of the report has calculated that these two mean values (100 and 120) are not statistically different at  $\alpha = 0.05$ , and has declared the dose of 35 to be the NOAEL. You want to know what the chances are that a t-test based on 8 animals in each experimental group (control, exposed) would have revealed a significant difference (i.e.,  $P < 0.05$ ) if the difference were as large as some value you select ( ). In this example, let the difference of concern to you be 25 (it could be any number that your feel would be biologically significant). Then, the power of the data to detect a difference of this size is calculated as follows:

Step 1: Calculate  $Z_{\delta}$

$$Z_b = 0.5 \left( \frac{25}{30} \right) \sqrt{16} - 1.645 = 0.0217$$

Step 2: Compare with Critical Value

Assume you wanted to be able to detect a true difference of 25 with a confidence of 80%. From the table above, the critical value for 80% power is 0.842. The calculated value of  $Z_{\delta}$  (0.0217) is smaller than the critical value, so the power of the test was less than 80%. By interpolation from the table above, it can be seen the power is somewhere between 50% and 75%.



If you wish, the precise probability associated with  $Z_{\frac{\alpha}{2}}$  can be looked up in a standard t-table, or can be calculated using a built-in function in most computer spreadsheet programs. In this case, the probability (power) is about 59%. That is, there was only a 59% chance that the results of the t-test based on a sample size of 8 in each group would have declared the exposed group different from the control group if the true difference were really 25. Based on this, the confidence that the identified NOAEL is really a no-effect level is only low to moderate.

Choosing the value of  $\delta$  to use in this calculation is subjective. For example, for some receptors and some endpoints, rather large effects (e.g., 30-40% of control) might not be of biological significance, while for other endpoints and other receptors, even small differences (e.g., 5-10%, or even less) might be of concern. For the purposes of evaluating toxicological studies as candidates for derivation of TRVs, a default value of 20% of control is used as  $\delta$ . This is based on the assumption that most experimental studies cannot detect smaller changes with acceptable power, and that changes of 20% or less will often not result in population level impacts, at least for many endpoints.

## Power Example:

<b>N Exp</b>	<b>10</b>	<b>20</b>	<b>25</b>	<b>10</b>	<b>25</b>	<b>30</b>	<b>200</b>	<b>10</b>
<b>N Cont</b>	<b>8</b>	<b>20</b>	<b>25</b>	<b>10</b>	<b>30</b>	<b>30</b>	<b>200</b>	<b>10</b>
<b>Mean Exp</b>	<b>95</b>	<b>56</b>	<b>5.6</b>	<b>8.9</b>	<b>5.6</b>	<b>56</b>	<b>5.6</b>	<b>2.3</b>
<b>Mean Cont</b>	<b>80</b>	<b>42</b>	<b>4.2</b>	<b>7.5</b>	<b>4.2</b>	<b>37</b>	<b>4.2</b>	<b>2.2</b>
<b>Stdev Exp</b>	<b>16</b>	<b>11.2</b>	<b>1.1</b>	<b>1</b>	<b>1.1</b>	<b>10</b>	<b>1.1</b>	<b>0.8</b>
<b>Stdev Cont</b>	<b>18</b>	<b>8.4</b>	<b>1.3</b>	<b>1</b>	<b>1.3</b>	<b>10</b>	<b>1.3</b>	<b>0.9</b>
<b>Alpha</b>	<b>0.05</b>	<b>0.05</b>	<b>0.05</b>	<b>0.05</b>	<b>0.05</b>	<b>0.05</b>	<b>0.05</b>	<b>0.05</b>
Z Alpha	1.645	1.645	1.645	1.645	1.645	1.645	1.645	1.645
Diff	0.2	0.2	0.2	0.2	0.2	0.2	0.2	0.2

$$N \text{ Tot} = N \text{ Exp} + N \text{ Cont}$$

$$\text{Delta Diff} = \text{Mean Cont} * 0.02$$

$$\text{Pooled Stdev} = \sqrt{\{[(N \text{ Exp} - 1) * \text{Stdev Exp}^2 + (N \text{ Cont} - 1) * \text{Stdev Cont}^2] / (N \text{ Exp} + N \text{ Cont} - 2)\}}$$

$$Z \text{ Beta} = [0.5 * (\text{Delta Diff} / \text{Pooled Stdev}) * \sqrt{N \text{ Tot}}] - Z \text{ Alpha}$$

<b>N Tot</b>	18	40	50	20	55	60	400	20
<b>Delta Diff</b>	16	8.4	0.84	1.5	0.84	7.4	0.84	0.44
<b>Pooled Stdev</b>	16.90414	9.899495	1.204159	1	1.213524	10	1.204159	0.851469318
<b>Z Beta</b>	0.362859	1.038282	0.821325	1.709102	0.921741	1.221008	5.33082	-0.489503391
<b>Power</b>	<b>&gt;50%</b>	<b>&gt;85%</b>	<b>&gt;75%</b>	<b>&gt;95%</b>	<b>&gt;80%</b>	<b>&gt;85%</b>	<b>&gt;99%</b>	<b>&lt;50%</b>

<b>If Z Beta is greater than...</b>	<b>Power is...</b>
0.000	>50%
0.674	>75%
0.842	>80%
1.036	>85%
1.282	>90%
1.645	>95%
2.326	>99%

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## Appendix 4-4

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# Ecological Soil Screening Level Guidance - Draft

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*Wildlife TRV Standard Operating Procedure # 3: Data  
Evaluation*

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*June 27, 2000*

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**Appendix 4-4**

**Wildlife Toxicity Reference Value**  
**Standard Operating Procedure (SOP) #3: Data Evaluation**

**for**

**Ecological Soil Screening Levels (Eco-SSLs)**

June 27, 2000



**Prepared for USEPA Region 8**

**by**

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## 1.0 INTRODUCTION

The United States Environmental Protection Agency (USEPA) Office of Emergency and Remedial Response (OERR) with a multi-stakeholder workgroup developed risk-based based soil screening levels (Eco-SSLs). Eco-SSLs are concentrations of contaminants in soils that are protective of ecological receptors that commonly come into contact with soil or ingest biota that live in or on soil. Eco-SSLs are derived separately for four groups of ecological receptors: mammals, birds, plants, and soil invertebrates. As such, these values are presumed to provide adequate protection of terrestrial ecosystems.

The Eco-SSLs are used in the baseline ERA process to identify the contaminants that need to be evaluated further in the characterization of exposure, effects and risk characterization. The Eco-SSLs are used during Step 2 of the Superfund ERA process, the screening-level risk calculation. This step normally is completed at a time when limited soil concentration data are available, and other site-specific data (e.g., contaminant bioavailability information, area use factors) are not available. It is expected that the Eco-SSLs will be used to screen the site soil data to identify those contaminants that are not of potential ecological concern and do not need to be considered in the subsequent baseline ERA.

Plant and soil biota Eco-SSLs were developed from available plant, soil invertebrate and microbial toxicity data. The mammal and bird Eco-SSLs were the result of back-calculations from a Hazard Quotient (HQ) of 1.0. The HQ is equal to the dose (associated with the contaminant concentration in soil) divided by a toxicity reference value (TRV). Generic food chain models were used to estimate the relationship between the concentration of the contaminant in soil and the dose for the receptor (mg per kg body weight per day). The TRV represents a numerical estimate of a no adverse level (dose) for the respective contaminant.

The procedure(s) for deriving the oral TRVs needed for calculation of Eco-SSLs for mammals and birds are contained within four standard operating procedures (SOPs):

- |        |  |
|--------|--|
| SOP #1 | Literature Search and Retrieval (Exhibit 4-1)                |
| SOP #2 | Literature Review, Data Extraction and Coding (Appendix 4-3) |
| SOP #3 | Data Evaluation (Appendix 4-4)                               |
| SOP #4 | Derivation of the Oral TRV (Appendix 4-5)                    |

This document serves as SOP #3 (Appendix 4-4) and describes the procedure for evaluation of data extracted from toxicological studies for applicability in the derivation of wildlife TRVs. The scored data is then used to derive TRVs for mammals and birds, according to the procedures outlined in SOP #4



(Appendix 4-5).

## **2.0 PURPOSE**

TRVs were derived from the available literature reporting the toxicity of a contaminant to different mammalian and avian species. The toxicological study results (there may be more than one result reported within a study) were identified for each contaminant based on the results of literature reviews implemented as described in Exhibit 4-1. Not all studies resulting from the literature search process are equally relevant to the derivation of oral TRVs.

The purpose of this SOP is to describe the procedure used for the review of attributes of a toxicological study that tend to increase or decrease their respective usefulness for the derivation of wildlife TRVs. The SOP establishes a standard system for scoring the relevance and reliability of the findings of each toxicological study result.

## **3.0 THE SCORING SYSTEM**

Each study identified as part of the data search (Exhibit 4-1) were evaluated based on the data extracted from the identified studies (described in Exhibit 4-2). In instances within one study where more than one “experiment” (i.e., different combinations of receptor, dose, exposure route, exposure duration, and endpoint) is reported, the individual "experiments" are scored separately so that each may be evaluated.

The scoring system assigns an “attribute” score ranging from zero (no merit in setting a TRV) to 10 (extremely valuable and relevant to setting a TRV) to each of 10 toxicological study attributes. The ten attributes of the toxicological study include data source, dose route, test substrate, the contaminant form, dose quantification, endpoint, dose range, statistical power, exposure duration and test conditions. The evaluation of each attribute is described in Section 4.0. Note that a low score does not necessarily imply the study itself was poor, only that the study design was not optimal for the narrow goal of developing an oral TRV.

The total score is calculated by adding the results of the evaluation of each attribute. The total score may range from a minimum of 36 to a maximum of 100. The total scores are interpreted as follows:

80 to 100	High confidence
71 to 79	Medium confidence
66 to 70	Low confidence
0 to 65	Not Used in Eco-SSL Derivation

The results of the scoring process will be used to evaluate and rank toxicological studies that will be

considered for use in the derivation of TRVs according to procedures specified in SOP #4.

## **4.0 EVALUATION AND SCORING OF STUDY ATTRIBUTES**

### **4.1 Data Source**

The source of the toxicological study (e.g., peer reviewed vs. non-peer reviewed) is not expected to be an indication of the quality of the study nor its applicability in use as part of the data set to derive a TRV. Many peer reviewed studies in the toxicological literature may have little or no merit in setting oral TRVs, and some non-peer reviewed studies may be excellent sources of data for the derivation of oral TRVs. It is a requirement, however, that all studies being considered for the derivation of a TRV must be acquired and reviewed in primary form. That is, secondary descriptions of a study should not be used. Secondary reports often contain errors of fact, include only a subset of all of the data and findings, and may contain interpretations or judgements not supported by the primary data.

Scoring factors:

- 10 = Primary source is acquired and reviewed
- 0 = Primary source is not acquired and reviewed

### **4.2 Dose Route**

The Eco-SSLs reflect the concentrations of contaminants in soil protective of oral exposure via ingestion of soil or food items. Therefore, toxicological studies that use oral exposure (water, food, gavage, capsule) are considered more relevant than studies using use other methods of administration (inhalation, interperitoneal injections, dermal, intravenous, subcutaneous). This is because the absorption, metabolism, distribution and excretion of a contaminant can vary widely by exposure medium, thereby having a strong influence on the administered doses (or concentrations) that do and do not cause adverse effects.

Dietary studies are preferred to other solid oral exposures via gavage or capsule. Such bolus doses do not generally reflect natural feeding behaviors and the solute carrier used to deliver the gavage dose can alter the kinetics of the tissue dose.

Scoring factors:

- 10 = Dietary
- 8 = Other oral, solid exposures (gavage, capsule)

- 5 = Other oral, liquid exposures
- 0 = Not oral (inhalation, intravenous, subcutaneous, dermal)

### 4.3 Test Substrate Concentrations

An important issue in evaluation of the quality of a toxicological study for use in wildlife TRV derivation is if nominal or measured concentrations of the contaminant in the exposure medium (diet in particular) are reported and used in the determination of the dose-response relationship in the study. Using only nominal concentrations can introduce a large error into the determination of a toxicity “threshold”. Studies that do not report measured concentrations are given less weight than those that provide measured concentrations.

The following scoring factors are applied:

- 10 = Test substance concentrations reported as actual measured values
- 5 = Test substance concentrations reported as nominal values
- 1 = Test substance concentrations calculated
- 0 = Test substance concentrations not reported

### 4.4 Consideration of Absorption Fraction and Contaminant Form

Oral TRVs are expressed in units of ingested dose (mg/kg-day). It is important to recognize that the use of a TRV expressed as units of ingested dose implicitly assumes that absorption of the contaminant from the test medium is the same as for the site medium. This assumption may be reasonable when the two media are the same (e.g., both water, both similar food items), but may not be true if the two media are different (e.g., test medium = water, site medium = soil). To account for the potential difference in absorption between different media, it is necessary to convert both the ingested dose and the TRV to units of absorbed dose:

Site Dose (absorbed) = Site Dose (ingested) @Absorption fraction from site medium

TRV(absorbed dose) = TRV(ingested dose) @Absorption fraction in test medium

For this reason toxicological studies reporting the known oral absorption fraction from the test medium are preferred to those where the absorption fraction is not known. If the absorption fraction is known (either from the TRV study itself or from other studies in the same test medium), then the TRV can be used to evaluate hazard from any other medium with a known or estimated absorption fraction. For the

Eco-SSLs it is conservatively assumed that absorption (bioavailability of the contaminant from the soil) is 100%.

The assumption equal absorption of the contaminant from the test and site medium is reasonable when the form of the contaminant is the same in the test medium versus the site medium. Some contaminants are more absorbed and more biologically active than others. The best known examples are differences between inorganic and organic mercury, inorganic and organic arsenic, chloride versus sulfate and oxide forms of other metals; and organoselenium versus selenite and selenate. The preferred toxicological studies use the same form of contaminant in the exposure medium compared to that found in the site medium. The contaminant form is considered in evaluation of the toxicological study according to the following scoring factors:

- |    |   |   |
|----|---|---|
| 10 | = | Contaminant form is known and is the same or similar to that found in the medium of concern |
| 5  | = | Contaminant form is irrelevant to absorption or biological activity                         |
| 4  | = | Contaminant form is not reported  |

#### **4.5 Dose Quantification**

Knowledge of the actual doses ingested by animals in a laboratory study (or field study) can often be imprecise, especially when the exposure route is via food or water. Many studies measure the amount of water or food consumed (water and food intake rates), and hence the average ingested dose (assuming there has been no loss of contaminant) can be calculated. However, some studies do not measure and do not report water or food intake rates. This can cause errors in dose estimation, especially in cases where the presence of the test contaminant in the water or food causes a direct reduction in intake due to taste aversion, odor aversion or illness. For wildlife TRV derivation studies which report actual doses are preferred over those where the doses need to be estimated based on reported intake rates and body weights.

Scoring factors:

- |    |   |  |
|----|---|--|
| 10 | = | Administered doses reported as mg per kg-BW  |
| 7  | = | Administered doses need to be calculated and intake rates and body weights provided.         |
| 6  | = | Administered doses need to be calculated and only one value (intake or body weight provided) |

- 5 = Administered doses need to be calculated based on estimated intake rates and body weights.
- 0 = Administered doses cannot be calculated from the information provided.

#### **4.6 Endpoint**

An important factor in the derivation of a TRV is consideration of the relevance of the toxicological study endpoint (measurement) to the assessment endpoint(s) established for the ecological risk assessment. In most ecological risk assessments, assessment endpoints focus on the effects of long term exposures of contaminants on population sustainability. The specific toxicological endpoints used as measurements of population sustainability in ERAs are site-specific and are dependant on many factors not limited to the types of receptors, contaminants and exposure routes.

For the purposes of identification and derivation of a TRV for calculation of an Eco-SSL, the endpoints have been predefined. The wildlife TRV is calculated based on chronic exposure data for reproduction and growth endpoints with chronic mortality also considered (Appendix 4-5). In the data evaluation scoring system chronic exposure data that measure reproductive endpoints are given the highest preference followed by chronic mortality and then growth. Other changes in “fitness” such as organ function, behavior, neurological function and biomarkers are provided consideration but are scored as a lower priority.

Scoring factors:

- 10 = Reported endpoint is a reproductive effect
- 9 = Reported endpoint is lethality (chronic and subchronic exposure)
- 8 = Reported endpoint is reduction in growth
- 4 = Reported endpoint is a sublethal change in organ function, behavior or neurological function
- 1 = Reported endpoint is a biomarker with unknown relationship to fitness

#### **4.7 Dose Range**

By definition, a TRV is intended to represent the location on the dose-response curve that is the threshold between absence and presence of the effect of concern (i.e., the toxicological endpoint selected as most relevant). There were two methodologies considered for establishing this threshold.

The first methodology involves identification of two values from the toxicological study including a no observed adverse effect level (NOAEL) and a lowest observed adverse effect level (LOAEL). The LOAEL is defined as the lowest administered dose that did cause a statistically significant adverse effect and the NOAEL as the lowest administered dose that did not cause a statistically significant adverse effect. Experimentally, the value of the threshold is estimated by assuming that it lies between the NOAEL and the LOAEL. Therefore, studies that use a series of doses that span the threshold region and which identify both a NOAEL and a LOAEL are much more valuable in estimating the threshold than a study which uses only one dose, or which uses multiple doses that do not bracket the threshold.

The second methodology involves the use of a modeling approach derived from the benchmark dose methodology being evaluated by EPA for use in human health risk assessment. This model estimates an exposure-response distribution. The dose level (and 95% confidence limits) are then identified from the distribution (e.g., ED<sub>5</sub> to ED<sub>50</sub>). This method was considered in the development of the wildlife TRVs for Eco-SSLs but was not used due to limitations in the dose-response data available for wildlife. This methodology may be considered further in future revisions of the wildlife TRV numbers.

In the case of both methodologies, the same type of scoring system for evaluation of dose-range applies as it is desirable to have the “threshold” bracketed. Any study that does not contain a suitable control group cannot be used to establish a dose-response value as the TRV for calculation of an Eco-SSL.

Scoring factors:

10	=	Both a NOAEL and a LOAEL are identified; values are within a factor of 3
8	=	Both a NOAEL and a LOAEL are identified; values are within a factor of 10
6	=	Both a NOAEL and a LOAEL are identified; values are not within a factor of 10
4	=	Only a NOAEL or a LOAEL is identified
0	=	Study lacks a suitable control group

#### **4.8 Statistical Power**

As noted above, a NOAEL is generally defined as the highest dose that did not cause a statistically significant effect in the selected endpoint compared to control. However, the ability to detect an effect (i.e., the reliability of the NOAEL) depends on a number of factors, most important of which are: 1) the variability of the measurement endpoint in both the control and the dosed groups, and 2) the number of

animals in each group. That is, as variability in the measurement endpoint goes up and the number of experimental animals goes down, the ability to detect an effect becomes very poor, and a dose which really does cause an effect may be incorrectly identified as a no-effect level.

There are a number of standard statistical procedures available for calculating the statistical power of a study to detect an effect, and these tests can be used to evaluate the reliability of NOAEL values. If the distributions of values in the control group and the exposed group are both approximately normal, and if the number of animals in the control and the exposed group are similar, then power of the NOAEL value can be estimated as follows.

First, calculate the value of  $Z_b$  from the following equation:

$$Z_b = 0.5 \left( \frac{\Delta}{s} \right) \sqrt{N} - Z_a$$

where:

$Z_b$  = Value of Z needed to detect a difference of  $\Delta$  with confidence  $\alpha$  and power  $\beta$  between the mean of two distributions each with standard deviation  $s$

$\Delta$  = Assumed difference between the exposed and control groups (i.e., the difference that is of concern to you as a biologically significant effect).

$s$  = Pooled standard deviation of exposed and control groups. When the number of samples in each group is the same, this is simply the square root of the average of the squares of the standard deviation for each group:

$$s = s_p = \sqrt{0.5 (s_1^2 + s_2^2)}$$

where:

$N$  = Number of animals in control plus exposed group combined.

$Z_a$  = Value of Z when the area to the right of Z on the standard normal curve is equal to  $100 \times (1 - \alpha)$ . For  $\alpha = 0.05$ , the value of  $Z_a$  is 1.645.

Then, compare the calculated value of  $Z_b$  to a critical value selected from the table below:

Power	Beta	Z <sub>b</sub> (Critical)
25%	0.75	-0.319
50%	0.50	0.000
75%	0.25	0.319
80%	0.20	0.842
90%	0.10	1.283
95%	0.05	1.645

If the calculated value of Z<sub>b</sub> is larger than the critical value, then the experimental data have the necessary power to detect a difference of concern (?) in approximately 100\*(1-β)% of all tests. If the calculated value is less than the critical value, the power of the test is below the target.

For example, suppose that you are reviewing a study where the following results are presented:

Parameter	Control	Exposed
Dose	0	35
Study Mean	100	120
Study Stdev	30	30
N	8	8

Using a standard one-tailed t-test, the author of the report has calculated that these two mean values (100 and 120) are not statistically different at alpha = 0.05, and has declared the dose of 35 to be the NOAEL. You want to know what the chances are that a t-test based on 8 animals in each experimental group (control, exposed) would have revealed a significant difference (i.e., P < 0.05) if the difference were as large as some value you select (?). In this example, let the difference of concern to you be 25 (it could be any number that your feel would be biologically significant). Then, the power of the data to detect a difference of this size is calculated as follows:

Step 1: Calculate Z<sub>b</sub>

$$Z_b = 0.5 \left( \frac{25}{30} \right) \sqrt{16} - 1.645 = 0.0217$$

Step 2: Compare with Critical Value

Assume you wanted to be able to detect a true difference of 25 with a confidence of 80%. From the table above, the critical value for 80% power is 0.842. The calculated value of Z<sub>b</sub> (0.0217) is smaller than the critical value, so the power of the test was less than 80%. By interpolation from the table above, it can be seen the power is somewhere between 50% and 75%.



If you wish, the precise probability associated with  $Z_8$  can be looked up in a standard t-table, or can be calculated using a built-in function in most modern spreadsheets. In this case, the probability (power) is about 59%. That is, there was only a 59% chance that the results of the t-test based on a sample size of 8 in each group would have declared the exposed group different from the control group if the true difference were really 25. Based on this, the confidence that the identified NOAEL is really a no-effect level is only low to moderate.

Choosing the value of  $\delta$  to use in this calculation may be difficult. For example, for some receptors and some endpoints, rather large effects (e.g., 30 to 40% of control) might not be of biological significance, while for other endpoints and other receptors, even small differences (e.g., 5-10%, or even less) might be of concern. For the purposes of evaluating toxicological studies as candidates for derivation of TRVs, a default value of 20% of control is recommended for  $\delta$ . This is based on the assumption that most experimental studies cannot detect smaller changes with acceptable power, and that changes of 20% or less will often not result in population level impacts, at least for many endpoints.

If standard error is reported but not the standard deviation then the standard deviation can be calculated using the standard error and the sample size as  $\text{StDev} = \text{StError} * \text{square root of } N$ .

Scoring factors:

10	=	At least 90% chance of seeing a difference that is biologically significant
8	=	At least 75% chance of seeing a difference that is biologically significant
6	=	At least 50% chance of seeing a difference that is biologically significant
3	=	Less than a 50% chance of detecting a difference that is biologically significant
1	=	STDEV and/or N not reported; the power of the NOAEL cannot be determined.

#### **4.9 Exposure Duration**

The usefulness of a study result for derivation of a TRV is partially dependent on the duration of the exposure. Chronic and multiple generation exposures are preferred to subchronic exposures. Acute exposures are defined as single oral exposures and other exposures of less than 14 days. Chronic exposures are generally more representative of the type of exposure which may occur at a contaminated site.

The Exposure Duration score is based on the duration of the study exposure and the lifespan of the test organism. A summary of typical laboratory test organism's lifespan is provided in Table 23 of Exhibit

4-2. If the exposure duration encompasses multiple generations of the test organism, a score of 10 is selected. If the duration of exposure is at least 0.1 times the expected lifespan of the test organism or occurs during a critical lifestage, a score of 10 is selected.

A lifestage is defined as critical if it is critical to the survival and reproduction of the species. These lifestages may or may not be more sensitive to contaminant exposure. Critical lifestages are listed in the following table. There may be some cases where professional judgement is used to classify certain exposures as critical outside of these listed. These instances are recorded as part of the data review and evaluation (coding) as described in Exhibit 4-2.

<b>Lifestage Code Descriptions</b>	
<b>Lifestage</b>	<b>Critical (Yes or No)</b>
adult	No
egg	Yes
embryo	Yes
immature	Yes
juvenile; includes yearling,	Yes
mature	No
multiple	Yes
not reported, unknown	No
subadult	No
sexually immature	No
sexually mature	No
young	Yes
young of year	Yes
Gestational Exposures	Yes
Lactation	Yes

To assess if the exposure duration is representative of the expected lifespan, the test organism lifespan is multiplied by 0.1. For example, if the test organism is a gerbil with an assumed lifespan of 2.5 years ( $2.5 \text{ years} * 0.1 = 0.25 \text{ years}$  or 12 weeks), an exposure duration of 9 weeks is less than 0.1 times the expected lifespan. If the duration of exposure is less than 0.1 times the expected lifespan of the test organism and multiple dosing intervals occur, a score of 6 is selected. If the duration of exposure is less than 0.1 times the expected lifespan and only a single dose interval occurs, a score of 3 is assigned. If the exposure duration is acute (a single oral dose), a score of 0 is selected.

Scoring:

- |    |   |  |
|----|---|--|
| 10 | = | Exposure duration encompasses multiple generations of test species   |
| 10 | = | Exposure duration is at least 0.1 times the expected life span of the test species or occurs during a critical life phase. |
| 6  | = | Exposure duration is shorter than 0.1 times the expected life span of the test species but multiple dosing intervals occur |
| 3  | = | Exposure duration is shorter than 0.1 times the expected life span of the test species and only one dose interval occurs.  |
| 0  | = | Acute exposure or single oral dose.  |

#### 4.10 Test Conditions

Many aspects of the conditions under which animals are subject to toxicity tests may affect the outcome of the endpoints being measured. Testing conditions including ambient or incubator temperature, lighting regime, food presentation and composition, age of test species and source of test species have all been shown to influence toxicity results. Therefore, it is important that these parameters be reported in the study so the potential for confounding effects can be evaluated. If studies are reported as having been conducted following standard test protocols (e.g., avian reproduction test method), and if the measured conditions are reported and meet target values, they can be considered as the highest quality study. Equally of high quality are studies that did not explicitly follow a standard protocol, but reported all test conditions. Studies that followed standard protocols but did not report the measured conditions are of secondary quality. Studies that report only some of the key test conditions are of lower quality while those that do not report any of the test conditions should not be used. Standard study protocols and test condition parameters are discussed in Exhibit 4-2 as part of the coding guidelines. Table 12 of Exhibit 4-2 provides a summary of the standard avian and mammalian testing protocols and the parameters measured for each.

Scoring factors:

- |    |   |   |
|----|---|---|
| 10 | = | Follows standard guideline and reports all measurement parameters     |
| 10 | = | Does not follow a standard guideline, but reports all test parameters |
| 7  | = | Follows a standard guideline but does not report test parameters      |

- 4      =      Does not follow a standard guideline and reports some, but not all of the test parameters
- 2      =      Does not report any test parameters

**TABLE 1 SUMMARY OF SCORING SYSTEM**

Attribute	Description	Score
Data source	Primary	10
	Secondary	0
Dose Route	Dietary	10
	Other oral (gavage, capsule)	8
	Other oral (liquid)	5
	Not oral or water (inhalation, intravenous, subcutaneous, dermal,etc.)	0
Test Substrate Concentration	Test substance concentrations reported as actual measured values	10
	Test substance concentrations reported as nominal values	5
	Test substance concentrations calculated	1
	Test substance concentrations not reported	0
Contaminant Form	Chemical form is known and is the same or similar to the of medium of concern	10
	Chemical form is irrelevant to absorption or biological activity	10
	Chemical form is known and is different from that found in the medium of concern	5
	Chemical form is not reported	4
Dose Quantification	Administered doses reported as mg/kg-BW	10
	Administered doses need to be calculated and intake rates and body weights provided	7
	Administered doses need to be calculated and only one value (intake or body weight) provided	6
	Administered doses need to be calculated based on estimated intake rates and body weights	5
	Administered doses cannot be calculated from the information provided	0
Endpoint	Reported endpoint is a reproductive effect	10
	Reported endpoint is lethality (chronic or subchronic exposures)	9
	Reported endpoint is reduction in growth	8
	Reported endpoint is sublethal change in organ function, behavior or neurological function	4
	Reported endpoint is a biomarker of exposure with unknown relationship to fitness	1
Dose Range	The study data can be used to estimate a dose-response relationship and an EC5 and confidence intervals can be estimated with the data presented	10
	Both a NOAEL and a LOAEL are identified; values are within a factor of 3	10
	Both a NOAEL and a LOAEL are identified; values are within a factor of 10	8
	Both a NOAEL and a LOAEL are identified; values are not within a factor of 10	6
	Only a NOAEL or a LOAEL is identified	4
	Study lacks a suitable control group	0
Statistical Power	At least 90% chance of seeing a difference that is biologically significant	10
	NOAEL and LOAEL available or LOAEL only available	10
	At least 75% chance of seeing a difference that is biologically significant	8
	At least 50% chance of seeing a difference that is biologically significant	6
	Less than a 50% chance of detecting a difference that is biologically significant	3
	Power of NOAEL cannot be determined	1
Exposure Duration	Exposure duration encompasses multiple generations of test species	10
	Exposure duration is at least 0.1 times the expected life span of the test species or occurs during a critical life phase	10
	Exposure duration is shorter than 0.1 times the expected life span of the test species but multiple dosing intervals occur	6
	Exposure duration is shorter than 0.1 times the expected life span of the test species and only a single dose exposure occurs.	3
	Exposure duration is acute	0
Test Conditions	Follows standard guidelines and reports all measurement parameters	10
	Does not follow a standard guideline, but does report all test parameters	10
	Follows a standard guideline but does not report test parameters	7
	Does not follow a standard guideline and reports some, but not all of the test parameters do not report any test parameters	4
		2

## 5.0 EXAMPLES

Both of the examples below are hypothetical and are intended to illustrate the basic approach that is recommended to assessing the relevance of toxicological data as the basis for deriving wildlife TRVs for use in establishing Eco-SSLs for wildlife.

### 5.1 Example 1

#### Study Summary

Smith and Jones (1984) performed a study on the effects of ingestion of dieldrin on reproduction of rats. Male and female Sprague-Dawley rats (10 per dose group) were provided with drinking water (*ad lib.*) that contained 0, 3, 10, 30, or 100 ug/L of dieldrin. Exposure began when the rats were three weeks old. At sexual maturity, males and females were randomly selected from within each dose group and were allowed to breed. After breeding, exposure of the females continued throughout gestation and lactation. The number of pups in each litter that survived to weaning was measured. Results are summarized below. Shaded cells are statistically different than control ( $p < 0.05$ ). This result is being considered for use for derivation of the TRV for the cottontail.

Dose Group (ug/L)	Viable pups per dam (mean " stdev)
0	7.1 " 2.1
30	7.3 " 2.2
100	6.8 " 1.9
300	6.0 " 2.4
1000	3.1 " 1.7

#### Evaluation of Study Attributes

Attribute	Description	Score
Data source	Primary report was obtained and reviewed	10
Dose Route	Oral (water)	5
Test Substance	Measured concentrations are reported	10
Contaminant Form	Contaminant form in exposure medium is the same as site medium.	10
Dose Quantification	Administered doses not quantified. Ingestion rate nor body weights reported. Some effects might be due to decreased water intake by dam due to taste aversion.	5
Endpoint	Reported endpoint is a reproductive effect	10
Dose Range	Both a NOAEL and a LOAEL are identified; values are within a factor of 3	10

Attribute	Description	Score
Statistical Power	NOAEL and LOAEL reported.	10
Study Duration	Exposure duration is at least 0.1 times the expected life span of the test species and occurs during a critical life phase.	10
Test Conditions	Follows standard guideline and reports all measurement parameters	10
<b>Total Score</b>		90

## 5.2 Example 2

### Study Summary

Adams and Baker (1993) performed a study on the effects of ingestion of cadmium on renal function in dogs. Male or female animals (3 per dose group) were provided with cadmium chloride in the diet at added concentration levels of 0, 100, or 1000 mg/kg. Based on measured dietary intake, dose levels were reported to be 0, 5.2, and 41.1 mg/kg-BW per day, respectively. Urinalysis was performed for urine samples collected at days 30, 60 and 90. At day 90, animals were sacrificed and the kidneys were examined histologically. The results are summarized below.

Dose Group (mg/kg-d)	Study Day	Urinalysis	Histopathology
5.2	30	No effect	--
	60	Mild proteinurea	—
	90	Moderate proteinurea	7% focal necrosis of renal tubule
41.1	30	Mild proteinurea	—
	60	Moderate proteinurea	—
	90	Severe proteinurea	Widespread necrosis of renal tubule

Based on these data, the authors stated that doses of 5.2 to 41.1 mg/kg-day for 90 days caused moderate to severe renal injury in dogs.

### Evaluation of Study Attributes

Attribute	Description	Score
Data source	Primary report was obtained and reviewed	10
Dose Route	Oral (diet)	10
Test Substrate	Measured concentrations are reported	10

Attribute	Description	Score
Contaminant Form	The contaminant form is the same or similar as the medium of concern.	10
Dose Quantification	Administered doses are reported as mg/kg-BW.	10
Endpoint	Reported endpoint is a sublethal change in organ function	4
Dose Range	Only a LOAEL was identified. No NOAEL can be estimated	4
Statistical Power	No NOAEL was identified; therefore this factor is not applicable	10
Exposure Duration	Exposure duration is shorter than 0.1 times the expected life span of the test species	6
Test Conditions	Does not follow a standard guideline and reports some, but not all of the test parameters	4
<b>Total Score</b>		<b>78</b>





## Appendix 4-5

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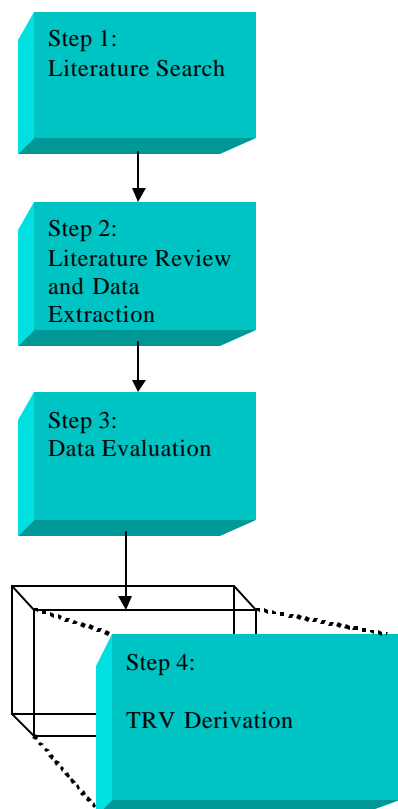
# Ecological Soil Screening Level Guidance - Draft

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### *Wildlife TRV Standard Operating Procedure # 4: Wildlife TRV Derivation*

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#### Wildlife TRV Derivation



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**Draft**

**Appendix 4-5**

**Wildlife Toxicity Reference Value  
Standard Operating Procedure (SOP) #4: TRV Derivation Process  
for  
Ecological Soil Screening Levels (Eco-SSLs)**

July 3, 2000



**Prepared for USEPA Region 8**

**by**

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## 1.0 INTRODUCTION

The United States Environmental Protection Agency (USEPA) Office of Emergency and Remedial Response (OERR) with the assistance of a multi-stakeholder workgroup developed risk-based ecological soil screening levels (Eco-SSLs). Eco-SSLs are concentrations of contaminants in soils protective of ecological receptors that commonly come into contact with soil or ingest biota that live in or on soil. Eco-SSLs are derived separately for four groups of ecological receptors: plants, soil invertebrates, birds and mammals.

Plant and soil invertebrate Eco-SSLs were developed from available plant and soil invertebrate toxicity data. The mammalian and avian Eco-SSLs were the result of back-calculations from a Hazard Quotient (HQ) of 1.0. The HQ is equal to the dose (associated with the contaminant concentration in soil) divided by a toxicity reference value (TRV). Generic food chain models were used to estimate the relationship between the concentration of the contaminant in soil and the dose for the receptor (mg per kg body weight per day). The TRV represents a numerical estimate of a no adverse level (dose) for the respective contaminant.

The procedure(s) for deriving the mammalian and avian oral TRVs needed for calculation of Eco-SSLs are contained within four standard operating procedures (SOPs):

SOP #1	Literature Search and Retrieval (Exhibit 4-1)
SOP #2	Literature Review, Data Extraction and Coding (Appendix 4-3)
SOP #3	Data Evaluation (Appendix 4-4)
SOP #4	Derivation of the Oral TRV (Appendix 4-5)

This document serves as SOP #4 and describes the procedure for derivation of the wildlife TRVs. The wildlife TRVs are derived using the results extracted from the toxicological data identified in SOP #1 using the data extracted as described in SOP #2 and the data evaluation scores for each result applied as described in SOP #3.

### **1.1 Purpose**

The purpose of the SOP is to provide a clear written description of the procedures for derivation of the wildlife TRVs used for the calculation of Eco-SSLs. The document is written with two primary objectives:

- 1) To allow the users of the Eco-SSL values to fully understand how the wildlife TRVs were derived including the basis for any assumptions used in the derivation process.



- 2) To allow users of the guidance to derive wildlife TRVs for additional contaminants for which Eco-SSLs are not available. This provides for reproducible and consistent results.

## **1.2 Scope**

The second section of this SOP discusses how the results from the preceding SOPs (literature search, data extraction and data evaluation) are to be presented. Section 3 describes the process for plotting the toxicological data (NOAEL and LOAEL values). Section 4 describes the process for derivation of the wildlife TRV based on the results of Sections 2 and 3. Section 5 provides references.

This SOP is written as the fourth part of the wildlife TRV derivation process and it is assumed that the reader is familiar with the preceding three portions of the process. The wildlife TRVs for the Eco-SSL contaminants derived to date are presented in Appendix 4-6. Some results are used in this SOP for illustration purposes.

### **Wildlife TRV Derivation Process**

The wildlife TRV derivation process is composed of four general steps:

- **Literature Search and Retrieval**  
*Wildlife TRV SOP 1: Literature Search and Retrieval* (Exhibit 4-1)  
A literature search identifies dose-response literature for retrieval.
- **Literature Review and Data Extraction**  
*Wildlife TRV SOP 2: Literature Review, Data Extraction and Coding* (Appendix 4-3).  
The retrieved literature studies are reviewed and data are extracted according to an established coding system. Data are entered into an electronic data base
- **Data Evaluation**  
*Wildlife TRV SOP 3: Data Evaluation* (Appendix 4-4).  
Each of the results identified in the reviewed literature is scored for quality and applicability for TRV derivation.
- **TRV Derivation**  
*Wildlife TRV SOP 4: TRV Derivation* (Appendix 4-5).  
This procedure plots the collective dose-response

## **2.0 PRESENTATION AND REVIEW OF THE TOXICOLOGICAL DATA**

### **2.1 Reporting the Results of the Literature Search**

The literature search and review results for each contaminant will be reported as three separate categories:

- 1) Literature from which useful toxicological data was identified and extracted (literature coded);
- 2) Literature rejected for use; and,
- 3) Literature identified in the search that could not be retrieved for review

Each of the citations on these lists are identified with a unique record number assigned as part of the data extraction process as described in Exhibit 4-2 (SOP 2). Citations on the “literature rejected” list are labeled with respective literature rejection criteria as described in Appendix 4-3 (SOP# 2).

The results of the literature retrieval process for all contaminants are also described in tabular format including the number of papers identified as the result of the initial search process (Exhibit 4-1) and the manual review of retrieved papers (review articles), the total number of papers retrieved but rejected for use; the total number of papers with useful data for mammals and birds, and the total number of papers that could not be located.

### **2.2 Reporting the Results of Data Review and Evaluation**

An electronic database was created to facilitate efficient and accurate data extraction from individual reviewed toxicological studies. This database is fully described as Exhibit 4-2. Extraction of the data directly into an electronic database facilitates the necessary sorting, searching and presentation of the data for the purposes of TRV derivation. A web-based data entry system was used allowing remote access by multiple reviewers from any computer with Internet capabilities. Entry to the site is password-protected and limited to only those individuals within the Eco-SSL workgroup responsible for data entry. All information entered is sent directly to the master database (temporarily housed at a USEPA Region 8 contractor ISSI) avoiding any quality assurance problems associated with merging multiple sources of information into one database. The web-based system provides for immediate access to the entered data with any changes to the database or data entry process being immediately reflected on the website. The toxicity and scoring data recorded in the system are reported for each contaminant as part of Appendix 4-6. The entire wildlife TRV database will be made available as part of the final Eco-SSL guidance.

The final results of the Eco-SSL wildlife toxicity data coding effort will be transferred to EPA Duluth for incorporation into the ECOTOX TERRETOX database. The coding guidelines used for the Eco-SSL Wildlife TRV effort follow the same basic structure as that used by EPA Duluth for TERRETOX. There are, however, some necessary additions and exclusions from the TERRETOX coding system. The TRV database is focused on extracting the no observed adverse effect level (NOAEL) and lowest observed adverse effect level (LOAEL) doses from each of the toxicological studies while the TERRETOX system is designed to record all toxicological results from the studies.

### **2.3 Organizing and Presenting the Data and Data Evaluation Scores**

The toxicity data is downloaded from the database into excel spreadsheet files for each contaminant using the tabular format provided in Table 2.1. One table is constructed for avian data and a second for mammalian data. The tables provide the essential information concerning each of the toxicity testing results. Table 2.1 provides an example of the output for mammals and antimony. The results are numbered sequentially and then sorted by general effect group, effect type and effect measure.

**Table 2.1**  
**Example of Tabular Output of Toxicological Data from TRV Database - Mammalian Toxicity Data For Antimony**

TEST INFORMATION			EXPOSURE INFORMATION											EFFECTS INFORMATION						DATA EVALUATION SCORES										
Result #	Test ID	Contaminant Form	Species	# of Conc/Doses	Conc/Dose Units	Method of Analyses	Route of Exposure	Exposure Duration	Duration Units	Age	Age Units	Lifestage	Sex	General Effect Group	Effect Type	Effect Measure	Response Site	NOAEL Dose (mg/kg/day)	LOAEL Dose (mg/kg/day)	Data Source	Dose Route	Test Substrate	Contaminant form	Dose Quantification	Endpoint	Dose Range	Statistical Power	Exposure Duration	Test Conditions	Total
1	224-Sb-Poon -ML-FD-1-BIO-1	Antimony potassium tartrate	rat	5	mg Sb/kg BW/day	M	DR	13	w	NR	NR	NR	F	BIO	CHM	GLUC	WO	0.64	6.1	10	5	10	5	10	1	8	10	10	4	73
2	224-Sb-Poon -ML-FD-1-BIO-2	Antimony potassium tartrate	rat	5	mg Sb/kg BW/day	M	DR	13	w	NR	NR	NR	F	BIO	ENZ	ALPH	WO	6.1	46	10	5	10	5	10	1	8	10	10	4	73
3	189-Sb-Hext -ML-FD-1-BIO-1	Antimony trioxide	rat	4	mg Sb/kg BW/day	M	FD	90	d	NR	NR	AD	M	BIO	CHM	TRIG	BL	421	1686	10	10	10	10	10	1	8	10	6	10	85
4	189-Sb-Hext -ML-FD-1-BIO-2	Antimony trioxide	rat	4	mg Sb/kg BW/day	M	FD	90	d	NR	NR	AD	M	BIO	ENZ	ALPH	BL	421	1686	10	10	10	10	10	1	8	10	6	10	85
5																														
6	224-Sb-Poon -ML-FD-1-BEH-3	Antimony potassium tartrate	rat	5	mg Sb/kg BW/day	M	DR	13	w	NR	NR	NR	F	BEH	FDB	WCONS	WO	6.1	46	10	5	10	5	10	4	8	10	10	4	76
7	189-Sb-Hext -ML-FD-1-BEH-3	Antimony trioxide	rat	4	mg Sb/kg BW/day	M	FD	90	d	NR	NR	AD	M	BEH	FDB	FCNS	WO	1686		10	10	10	10	10	4	4	1	6	10	75
8																														
9	248-Sb-Marmo-ML-DR-1-PHY-1	Antimony chloride	rat	3	mg%	U	DR	22	d	NR	NR	AD	BH	PHY	PHY	VASO	WO	6.1	61	10	5	5	10	6	4	8	10	6	4	68
10	189-Sb-Hext -ML-FD-1-PHY-4	Antimony trioxide	rat	4	mg Sb/kg BW/day	M	FD	90	d	NR	NR	AD	F	PHY	PHY	EXCR	WO	494	1879	10	10	10	10	10	4	8	10	6	10	88
11																														
12	224-Sb-Poon -ML-FD-1-PTH-4	Antimony potassium tartrate	rat	5	mg Sb/kg BW/day	M	DR	13	w	NR	NR	NR	F	PTH	HIS	FIBR	WO	6.1	46	10	5	10	5	10	4	8	10	10	4	76
13	270-Sb-Ainsw-ML-FD-1-PTH-2	Antimony trioxide	mouse	3	mg/kg diet	U	FD	18	d	NR	NR	NR	NR	PTH	ORWT	ORWT	KI	60	810	10	10	5	10	6	4	4	10	6	4	69
14	226-Sb-Diete-ML-DR-1-PTH-1	Antimony potassium tartrate	mouse	6	mg/kg BW/day	U	DR	14	d	6	w	NR	F	PTH	HIS	GSLN	WO	107	148	10	5	5	5	10	4	10	10	6	4	69
15	189-Sb-Hext -ML-FD-1-PTH-5	Antimony trioxide	rat	4	mg Sb/kg BW/day	M	FD	90	d	NR	NR	AD	M	PTH	ORWT	ORWT	LI	421	1686	10	10	10	10	10	4	8	10	6	10	88
16	189-Sb-Hext -ML-FD-1-PTH-6	Antimony trioxide	rat	4	mg Sb/kg BW/day	M	FD	90	d	NR	NR	AD	M	PTH	HIS	GHIS	LI	1686		10	10	10	10	10	4	4	1	6	10	75
17																														
18	231-Sb-Rossi-ML-DR-1-REP-2	Antimony trichloride	rat	3	mg/dl	U	DR	38	d	22	F	NR	M	REP	REP	PRWT	WO	0.01	0.1	10	5	5	10	6	10	8	10	6	4	74
19	5-Sb-James-ML-OR-1-REP-1	Antimony potassium tartrate	sheep	2	mg/kg BW/day	U	OR	155	d	1	y	NR	F	REP	REP	PROG	WO	0.73		10	8	5	5	10	10	4	1	10	4	67
20	225-Sb-Gurna-ML-GV-1-REP-1	Antimony trioxide	mouse	4	mg/kg BW/day	M	GV	21	d	8	w		M	REP	REP	SPCV	WO	335	559	10	8	10	10	10	10	10	10	6	4	88
21																														
22	231-Sb-Rossi-ML-DR-1-GRO-3	Antimony trichloride	rat	3	mg/dl	U	DR	38	d	22	F	NR	M	GRO	GRO	BDWT	WO	0.11		10	5	5	10	6	8	4	10	6	4	68
23	224-Sb-Poon -ML-FD-1-GRO-5	Antimony potassium tartrate	rat	5	mg Sb/kg BW/day	M	DR	13	w	NR	NR	NR	F	GRO	GRO	BDWT	WO	6.1	46	10	5	10	5	10	8	8	10	10	4	80
24	189-Sb-Hext -ML-FD-1-GRO-7	Antimony trioxide	rat	4	mg Sb/kg BW/day	M	FD	90	d	NR	NR	AD	M	GRO	GRO	BDWT	WO	1686		10	10	10	10	10	8	4	10	6	10	88
25																														
26	5-Sb-James-ML-OR-1-MOR-2	Antimony potassium tartrate	sheep	2	mg/kg BW/day	U	OR	155	d	1	y	NR	F	MOR	MOR	MORT	WO	0.7		10	8	5	5	10	9	4	1	10	4	66
27	221-Sb-Ainsw-ML-FD-1-MOR-3	Antimony trioxide	vole	2	mg Sb/kg diet	U	FD	60	d	35	d	NR	M	MOR	MOR	MORT	WO	70		10	10	5	10	7	9	4	1	6	4	66
28	226-Sb-Diete-ML-DR-1-MOR-2	Antimony potassium tartrate	mouse	6	mg/kg BW/day	M	DR	14	d	6	w	NR	F	MOR	MOR	MORT	WO	107	148	10	5	10	5	10	9	10	10	6	4	79
29	225-Sb-Gurna-ML-GV-1-MOR-3	Antimony trioxide	mouse	4	mg/kg BW/day	M	GV	21	d	8	w	NR	M	MOR	MOR	MORT	WO	559	839	10	8	10	10	10	9	10	10	6	4	87
30	221-Sb-Ainsw-ML-FD-2-MOR-1	Antimony trioxide	vole	3	mg Sb/kg diet	U	FD	12	d	35	d	NR	M	MOR	MOR	MORT	WO	2812		10	10	5	10	7	9	4	1	6	4	66
31	270-Sb-Ainsw-ML-FD-2-MOR-1	Antimony trioxide	vole	3	mg/kg diet	U	FD	21	d	NR	NR	NR	NR	MOR	MOR	MORT	WO	942		10	10	5	10	10	9	4	1	6	4	69

### 3.0 SUMMARY PLOTS OF TOXICOLOGICAL DATA

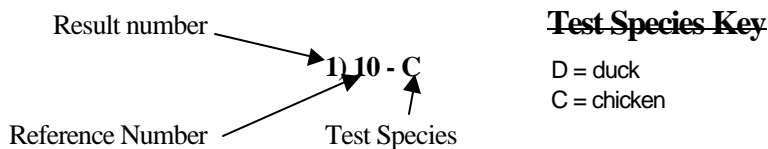
The data downloaded from the database into Excel spreadsheets is used to produce summary plots depicting the toxicological data (NOAEL and LOAEL results) for each contaminant. Summary plots are constructed separately for mammalian and avian toxicological data.

#### 3.1 Sorting by Endpoint

The data plots are organized by General Effect Group (described in Appendix 4-3) in order from left to right as:

- Biochemical (BIO)
- Behavioral (BEH)
- Physiological (PHY)
- Pathology (PTH)
- Reproduction (REP)
- Growth (GRO)
- Morality (MOR)

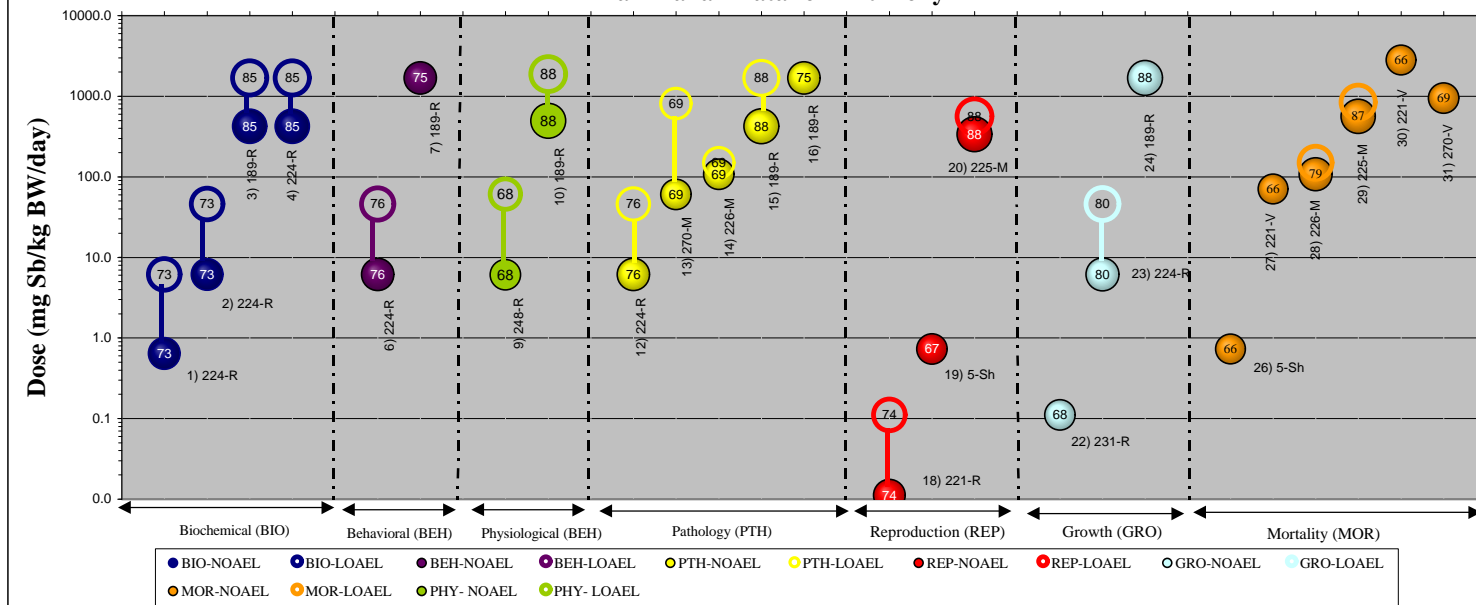
Figure 3.1 provides an example plot showing the mammalian dose-response data for antimony. The toxicity data associated with the plot is provided earlier as Table 2.1. The plot shows each study NOAEL and LOAEL result. NOAEL results are shown as closed circles while the LOAEL results are shown as open circles. Paired NOAEL and LOAEL values are connected by a vertical line. Within each of the circles the data evaluation score is shown and to the right of each circle the following label is



shown:

The labels allow the reader to examine the plotted data and identify the relative results for different species as well as results that come from the same study. The result number allows the reader to associate that data point back to the associated toxicity data table describing more specific information for that test result.

**Figure 3.1 Example of Summary Plot of NOAEL and LOAEL Values  
Mammalian Data for Antimony**



Result number → 1) 10 - C  
Reference Number →  
Test Species →

**Test Species Key**

Sh = sheep Pg = pig  
R = rat V = vole  
M = mouse

### **3.2 Exclusion of Data Considered Less Applicable for Deriving a TRV**

Each test result extracted during the literature review process is scored for quality and applicability for TRV derivation according to a data evaluation process as described in SOP #3 (Appendix 4-4). In instances where more than one “experiment” (i.e., different combinations of receptor, dose, exposure route, exposure duration, and endpoint) are reported in a study, the individual “experiments” were scored separately. In cases of more than one experiment, the scoring system is applied independently to each experimental result.

The scoring system is based on evaluation of ten attributes of the toxicological study and assigns a score for each attribute, ranging from zero (no merit in setting a TRV) to 10 (extremely valuable and relevant to setting a TRV). Note that a low score does not necessarily imply the study itself is poor, only that the study design is not optimal for the narrow goal of deriving an oral TRV. The total score was calculated by adding the results of the evaluation of each attribute. Data not used for TRV derivation are defined as study endpoints receiving a Total Data Evaluation Score of 65 or less. These data points are excluded from the plots. The purpose of the exclusion is to ensure that TRV derivation uses the most suitable data. The data evaluation process and rationale is provided as SOP #3 (Appendix 4-4).

### **3.3 Exclusion of Repetitive Values**

Within each toxicological study there may be several effect measures reported that have the same NOAEL and/or LOAEL values. Inclusion of the NOAEL and LOAEL results for all endpoint measures may result in repetitive values. To avoid the inclusion of repetitive and duplicative data, the results for only one Effect Measure per Effect Type are recorded in the plots. For example a study provides the following results for the biochemical effect group (BIO):

<b>General Effect Group</b>	<b>Effect Type</b>	<b>Effect Measure</b>	<b>NOAEL</b>	<b>LOAEL</b>
BIO	CHM	TRIG	<b>5</b>	<b>10</b>
BIO	CHM	GLUC	5	10
BIO	ENZ	ALPH	<b>5</b>	<b>10</b>
BIO	ENZ	ACHE	5	10

There are results for two effect measures reported within the effect type “chemical” (CHM) and “enzyme” (ENZ). In this case only one set of results for each “Effect Type” would be recorded on the plot and these are indicated in bold face type and shading.

## **4.0 PROCESS FOR DERIVATION OF WILDLIFE TRVs**

### **4.1 TRV Definition**

For the purposes of establishing the Eco-SSLs, the wildlife TRVs were defined by the workgroup as:

*Doses above which ecologically relevant effects might occur to wildlife species following chronic dietary exposure and below which it is reasonably expected that such effects will not occur.*

### **4.2 Goals and Assumptions**

The following underlying goals and assumptions guided the development of the TRV derivation process.

#### ***Use Chronic Exposure Data***

The Wildlife TRV should be based on chronic effects data and not acute or subacute toxicity information (exposures of 3 days or less in duration). The purpose for exclusion of acute toxicity data was to focus efforts on establishing a dose protective of most species from adverse effects associated with long term exposures and sublethal reproductive and growth effects. A chronic exposure duration is that of sufficient length to reveal most adverse effects that will occur, or would be expected to occur, over the lifetime of an exposed organism (NAS, 1980; USEPA, 1985).

#### ***Consider All Toxicological Information.***

The TRV should be based on the examination of all toxicological data extracted. These data are plotted and examined in a weight-of-evidence fashion as described in Section 4.4. The TRVs should not be based on the selection of a single “critical” study.

#### ***Consider Only Results for Dietary or Other Oral Exposures.***

The wildlife TRVs should consider only oral dose response data. These data are considered the most relevant to establishing soil screening levels that are protective of potential oral exposures (ingestion of soil or food). Toxicological data for non-oral exposure routes was excluded from the literature search and literature evaluation processes as described in Exhibit 4-1 and 4-2.

### **4.3 Methods Considered for TRV Derivation**

The task group responsible for derivation of wildlife TRVs considered many different approaches for establishing these values. Some, but not all, of the methods considered are discussed here to provide context for the method developed for TRV derivation.



### ***Critical Study Approach***

One method considered was the selection of a critical study result for each contaminant for mammals and birds. The study result would then be used as the TRV or a series of extrapolation and/or uncertainty factors would be applied to the critical study result to achieve the TRV. Factors are typically applied for “normalization” of the data such as approximating the chronic result from either acute or subchronic exposure data or approximating the NOAEL from the LOAEL. Other factors can be applied to the critical study result to account for “uncertainty” and ensure the protectiveness of the value and this would include factors for interspecies sensitivity. The critical study approach is currently used by EPA for human health risk assessments with toxicity values made available in the Integrated Risk Information System (IRIS). The critical study approach was also used in the derivation of wildlife criteria for the Great Lakes Water Quality Initiative (GLI) (USEPA, 1995); by Sample et al. (1996) for the derivation of wildlife screening benchmarks for the Oak Ridge National Laboratory Reservation; and by the Canadian Council of Ministers of the Environment (CCME) for soil quality guidelines for livestock and wildlife (CCME, 1997).

The Eco-SSL task group chose to use a broader “weight-of-evidence approach”(further described in Sections 4.4 and 4.5) that considered all of the extracted toxicological data in place of the selection of one critical study. The use of the critical study approach would require considerable professional judgement thereby decreasing the transparency and reproducibility of the wildlife TRV derivation process. To avoid foreseen conflicts over selection of “one” result; to prevent the need for “committee” selection and to attain transparency and reproducibility this method was not selected.

### ***Benchmark Dose Approach***

In recent years, the benchmark dose approach has been examined for use in human health risk assessments in place of NOAEL and LOAEL approaches (Rees and Hattis, 1994; USEPA, 1995). The benchmark dose is defined by EPA as the statistical lower confidence limit for a dose that produces a predetermined change in response rate of an adverse effect (called benchmark response) compared to background (USEPA, 1995).

Use of a benchmark dose method requires not only the selection of a critical study but also the critical or benchmark response within that study that would be modeled. It is also necessary to select the appropriate model or model(s) for the experimental data to derive the benchmark dose. The benchmark dose approach has not been adopted for use by the ecological risk community and a margin of safety or the acceptable “predetermined change in response rate”has not been identified by the regulatory community. With these limitations as well as those discussed for the critical study approach, the benchmark dose approach was not selected for derivation of the wildlife TRVs for Eco-SSLs.

## *Distribution Approaches*

Using distributions to represent the species sensitivities to contaminants is commonly used. The approach assumes that “...sensitivity of species is a stochastic variable that can be characterized by fitting a probability density function to test endpoints (e.g., LD50's LC50's for several species (Suter, 1993). This approach is used to establish soil standards in the Netherlands (Van Straalen and Denneman, 1989). Uncertainty is incorporated in the determination of confidence limits for thresholds protective of a fixed percentage of species (Van Straalen and Denneman, 1989; Aldenberg and Slob, 1993). As the sample size of the number of species tested increases, the protection threshold also increases.

Forbes and Forbes (1993) provides a review of the limitations of the distribution-based extrapolation models. The authors question the underlying assumptions of these models including: 1) “the distribution of species sensitivities in natural ecosystems closely approximates the threshold distribution”; 2) “the sensitivity of species used in laboratory tests provide an unbiased measure of the variance and mean of the sensitivity distribution of species in natural communities”; 3) “by protecting species composition, community function is also protected”; and 4) “interactions among species in communities and ecosystems can be ignored”.

Within the ECOFRAM guidelines a distribution based approach is used to predict the 5<sup>th</sup> percentile of the species sensitivity distribution based on the oral LD50 or LC50. With birds the minimum number of species required to use the distributional approach for species sensitivity is established by Luttik and Aldenberg (1995) at four. When N is equal to 4 or more species the parameters of the distribution are determined by the use of extrapolation factors from Aldenberg and Slob (1993). In cases, where n is less than four, then the 5<sup>th</sup> percentile is predicted based on pre-determined extrapolation constants that compensate for small sample size (ECOFRAM, 1999).

The distributional methods recommended for use in ECOFRAM are not however recommended for use with the avian reproduction study (a 14 day exposure) as the toxic mechanisms are different from the ones involved with acute toxicity. In a review of reproduction studies done with the Mallard and Bobwhite Quail by Mineau, Boersma and Collins (1994) the developmental effects differed significantly between the two species and there was greater similarity between the rat and bird results than between that of the two bird species. This suggests a limited ability to extend the results of the avian reproductive test or any other chronic test that identifies no-effect and low-effect values to other bird species.

The use of distributional approaches is also limited by the non-comparability of the results reported for chronic exposures in the literature. The literature available reporting chronic toxicity of contaminants to laboratory test animals and wildlife reflects a wide range of endpoints, exposure durations, test species, exposure routes, test conditions and all (most) using different non standardized testing protocols. The chronic testing results are consequently non-comparable and inappropriate for plotting as a distribution.

The distributional approach advocated for use within ECOFRAM and others is dependant upon the availability of comparable results (LD<sub>50</sub> values) from a standard toxicity testing protocol with the same toxicity endpoint, exposure duration, test species, exposure route and test conditions.

As a result of the earlier stated deficiencies and concerns with distributional approaches, and primarily the lack of an adequate toxicological database, the distributional approach was not selected for use.

### ***Weight-of-Evidence Approach***

In a weight-of-evidence approach the TRV would be selected based on the preponderance of the data. With this approach, all toxicological data (NOAELs and LOAELs) extracted (Appendix 4-3) from the studies identified in the literature review (Exhibit 4-1) and determined to be appropriate in establishing a TRV (as described in Appendix 4-4) would be plotted and the relative magnitude of the results examined to identify a threshold that would be protective. Examination of the dose-response data replaces the use of extrapolation factors as recommended by Chapman et al. (1998). The use of this method avoids the problems previously discussed with regard to the critical study approach.

## **4.4 Derivation Method Selected**

The specific method selected for use in the derivation of TRVs is a “weight-of-evidence” approach that includes the use of some factors (adjustments) to account for uncertainties. All NOAEL and LOAEL values extracted (Appendix 4-3) from studies identified in the literature review (Exhibit 4-1) and scored according to the data evaluation scoring procedure (Appendix 4-4) are plotted as described in Section 3.0. The resulting relative magnitude of the NOAEL and LOAEL values by effect type (biochemical, behavioral, physiological, pathology, growth, reproduction and mortality) are examined in a relative manner to identify or calculate a threshold value as the TRV according to the specific procedure described in Section 4.5. In most cases the TRV is equal to the weighted geometric mean of adjusted NOAELs for GRO and REP effects. The use of NOAEL and LOAEL values as the basis of the wildlife TRV derivation process is deemed a reasonable and effective approach when these values are presented across multiple studies, species, and endpoints as depicted in the toxicological plots (Figure 3.1).

The LOAEL is defined as the lowest concentration (or dose) at which statistically significant adverse effects are observed in the test organism compared to controls. The No-observed adverse effect level (NOAEL) is defined as the highest experimental dose that is not associated with significant adverse effects in the test organism compared to controls.

The process developed for derivation of the wildlife TRVs was designed specifically to address some of the stated limitations and concerns in using NOAEL and LOAEL results for establishing threshold dose-response values. These limitations and concerns are previously discussed in several publications (Chapman et al., 1998; USEPA, 1995; Hoekstra and Van Ewijk, 1993; Chapman et al., 1996;

Dhaliwal et al., 1997; and Chapman and Chapman, 1997). Some of the stated concerns and how they are addressed by the process are discussed as the following bullets:

- 1) The experimental dose referred to as the NOAEL is often based on judgement. The process developed for extraction of toxicity data (the NOAEL) (Appendix 4-3) and the data evaluation score (Appendix 4-4) include clear guidance on how to choose or select the NOAEL value from the toxicological study. The NOAEL and LOAEL results are examined to ensure they are accurately represented by the author. Primarily, the adequacy of the statistics used and the absence or presence of a dose dependant response are evaluated and considered in the identification of the NOAEL.

The evaluation of the experimental design includes the dose ranges and statistical power. NOAELs with lower statistical power and wider or fewer dose ranges are given lower data evaluation scores. NOAELs with a data evaluation score of 65 (out of 100) or less are not used in the derivation of the TRV. The NOAELs above 65 are “adjusted” based on the data evaluation score (as described in Section 4.5) to account for uncertainty in the value (the lower the score the more the NOAEL is lowered). The data evaluation score is then used to weight the NOAEL result in the calculation of the TRV (the higher the data evaluation score the more influence of the result in the mean).

- 2) Experiments involving fewer animals tend to produce higher NOAELs and thus higher TRVs. The statistical power of the NOAEL is determined in part by the number of experimental animals. In the TRV derivation process, NOAELs with lower statistical power are given lower data evaluation scores which are used in the adjustment of NOAEL values and the weighting of the value in the calculation of the TRV (Section 4.5). Also, the examination and use of NOAELs from multiple studies and multiple endpoints (in place of one study result) reduces the influence of any one study design in the calculation of the TRV.
- 3) The slope of the dose response curve plays little role in determining the NOAEL. The goal of the wildlife TRV derivation process is to identify a “no effect” concentration for purposes of deriving a soil screening value. Ideally, this “no effect” level should be close to the threshold for effects but this may not be true and the NOAEL consequently may be too low. As the wildlife TRV is based on multiple NOAELs across many studies and endpoints, this type of error for any individual study result is considered to be of little consequence.
- 4) The NOAEL cannot be used to characterize the magnitude of effects. The NOAEL value cannot be used to characterize the magnitude of any adverse effects. This is why LOAEL values are also included in the wildlife TRV process as a point of comparison with NOAELs and are also used to identify the TRV.

- 5) The NOAEL is affected by study design including the number and spacing of doses, endpoints measured and the number of replicates in each dose. The dose-response curve is also influenced by the study design. The examination and use of NOAELs from multiple studies and multiple endpoints (in place of one study result) reduces the influence of any one study design in the calculation of the TRV.

The use of NOAEL and LOAEL values as the basis of the wildlife TRV derivation process is deemed a reasonable and effective approach when these values are presented across multiple studies, species, and endpoints as depicted in the toxicological plots (Figure 3.1). These results are examined in a relative manner to identify or calculate a threshold value as the TRV according to the specific procedure described in Section 4.5. The minimum data sets required for the procedure as well as the consideration of interspecies sensitivity are described in the following subsections.

#### **4.4.1 Minimum Data Set Required to Derive a Wildlife TRV**

The task group identified a minimum data set required for derivation of either the mammalian or avian TRV. This minimum data set was based on discussions within the workgroup and best professional judgment. Once the toxicological study data is reviewed and input into the wildlife TRV database (Appendix 4.3) the data will be examined to evaluate intraspecific sensitivity. This analysis may result in changes to the minimum data set. The required data set consists of three NOAEL or LOAEL results for at least two test species for either growth (GRO); reproduction (REP) or survival (MOR) effects.

The minimum data set is generally consistent with minimum data sets established for other soil and risk guidelines. The Canadian Soil Quality Guidelines (CCME, 1997) requires a minimum of three studies for calculation of soil quality guidelines for soil and food ingestion for livestock and wildlife. There is a further requirement that at least two of these studies be oral mammalian studies and one must be an oral avian study. A maximum of one laboratory rodent study may be used to fulfill the data requirements for mammalian species if needed. Toxicity testing of pesticides prior to registration generally requires only one or two standard test species (ECOFRAM, 1999). However, the minimum number of avian species required to use the distributional approach for species sensitivity is established by Luttik and Aldenberg (1995) at four.

#### **4.4.2 Interspecies Sensitivity**

For technical and fiscal reasons only a few species of wildlife can be tested for toxicity of contaminants. Only rarely are test species the same as those likely to be exposed under field conditions. This fact implies that test results from standard test species need to be extrapolated to most field species.

Several investigators have examined the inter-species sensitivity of avian species to pesticides. The interspecies extrapolation methods recommended by ECOFRAM as part of the FIFRA risk assessment methods are based on analyses of 20 years of acute oral toxicity studies (LD50 study) on

pesticides. The oral LD50 data reflects a large number of tests completed for many species for numerous compounds using only one well established test protocol. Analysis of this data by Baril et al. (1994) resulted in the following observations:

- (1) Ranking of species sensitivities tends to persist across chemicals
- (2) Red-winged blackbirds are the most sensitive followed as a group by the Common Grackle, the House Sparrow, the Mallard and the Rock Dove. A second group including the Pheasant, Japanese Quail and the Starling are the least sensitive.

Other authors (Joermann, 1991; Schafer and Brunton, 1979; and Tucker and Haegele, 1971) have also evaluated phylogenetic patterns in sensitivity of avian species to pesticides. These studies have demonstrated some patterns of sensitivity between some families of birds across pesticides. However, each species shows a wide range of sensitivity among the same pesticides. ECOFRAM concludes that there are probably enough exceptions to prevent the development of a predictive approach based on phylogenetic relationships. They did conclude that two groupings of species (based on taxonomic relationships) could be separated according to sensitivity (acute) to cholinesterase-inhibiting chemicals (ECOFRAM, 1999).

As more data becomes available in the Wildlife TRV database, interspecies sensitivity will be further examined by comparison of bounded LOAEL values between species by contaminant. This approach is similar to that used to examine the use of uncertainty factors for wildlife criteria in the GLWQI. If the current minimum data set is deemed underprotective then the minimum data set and the use of additional uncertainty factors will be re-evaluated.

#### **4.5 Specific Procedure for Derivation**

The general steps and conditional statements of the derivation process are outlined in Figure 4.1. These steps are an a priori framework for selection or calculation of the TRV value based on the results of the NOAEL and LOAEL data plots. The flow chart is used with the toxicological data plots to derive the TRV according to the following described steps.

**Step 1: Are there at least 3 results and 2 species tested for reproduction (REP), growth (GRO) or mortality (MOR) general effect groups?**

The minimum data set required to derive either a mammalian or avian TRV consists of three results (NOAEL or LOAEL values) for REP, GRO or MOR for at least two mammalian or avian species. If these minimum results are not available then a TRV will not be derived.

**Step 2: Are there 3 or More NOAELs in REP and GRO Effect Groups?**

Calculation of the weighted geometric mean NOAEL for REP and GRO requires at least three NOAEL results from either of the GRO and REP effect groups. If three or more NOAEL results are available then the user proceeds to Step 4. If there are less than three NOAEL results, then the user proceeds to Step 3.

**Step 3: Is there at least one NOAEL for REP and GRO?**

If there is at least one NOAEL result available for the REP and GRO effect groups, then the TRV is equal to the lowest reported NOAEL for either effect group (GRO or REP). In cases where this NOAEL is higher than the lowest LOAEL for the MOR effect group then the TRV is equal to the highest NOAEL below the lowest LOAEL for the MOR effect group or the lowest LOAEL which ever is lower.

**Step 4: Calculate a weighted geometric mean of adjusted NOAELs for GRO and REP Effect groups.**

The weighted geometric mean of the adjusted NOAELs is calculated according to the following steps and is illustrated in Table 4.1:

- A. The NOAEL results for GRO and REP are compiled with respective Total Data Evaluation Scores (columns 1, 2 and 3).
- B. The NOAEL values are adjusted based on their respective data evaluation score. The adjusted NOAEL value (column 4) for each endpoint is calculated as:

$$\text{Adjusted NOAEL} = \text{NOAEL} * (\text{Data Evaluation Score} / 100)$$

- C. The weighted geometric mean of the adjusted NOAEL values is calculated as shown in Table 4.1 and is equal to:

$$\log (\text{GeoMean}) = \{ \text{score}(1) * \log (\text{adj. NOAEL}(1)) + \dots + \text{score} (n) * \log (\text{adj. NOAEL}(n)) \} / \{ \text{sum of scores} \}$$

:

The adjustment of the individual NOAEL values according to the respective data evaluation score results in lowering the NOAEL by the percentage it does not attain the ideal score of 100. For example, a NOAEL of 10 mg/kg BW /day with a data evaluation score of 66 would be adjusted (lowered) to 6.6 while a NOAEL of 10 mg/kg BW/day with a data evaluation score of 80 would be adjusted (lowered) to 8 mg/kg BW/day. This adjustment is essentially an uncertainty factor applied to the individual NOAEL.

The weighted geometric mean is then calculated for the adjusted NOAEL values such that the values with the higher data evaluation scores (more appropriate data for establishing a TRV) have a greater influence in the mean.

<b>Table 4.1</b> <b>Example Calculation of Weighted Geometric Mean of Adjusted NOAELs</b> <b>Mammalian TRV Derivation for Antimony</b>					
(1)	(2)	(3)	(4)	(5)	(6)
Test ID	NOAEL	Data Evaluation Score	Adjusted NOAEL Value	Weight	Weight*Log Adj NOAEL
231-Sb-Rossi-ML-DR-1-REP-2	0.011	74	0.008	74	-154.29
5-Sb-James-ML-OR-1-REP-1	0.73	67	0.5	67	-20.84
225-Sb-Gurna-ML-GV-1-REP-1	335	88	295	88	217.36
231-Sb-Rossi-ML-DR-1-GRO-3	0.11	68	0.1	68	-76.28
224-Sb-Poon -ML-FD-1-GRO-5	6.13	80	4.9	80	55.24
189-Sb-Hext -ML-FD-1-GRO-7	1686	88	1484	88	279.08
Sum				465	300.28
(Sum of weight*log (adj NOAEL) / Sum of Weights					0.6458
Weighted Geometric Mean					4.4

### Is the Weighted Mean NOAEL < the Lowest LOAEL for MOR?

In some cases the weighted mean NOAEL (REP and GRO) may be higher than the lowest LOAEL (established effect level) for mortality or survival. In other words, mortality may be a more sensitive endpoint compared to reproduction or growth. In these instances, it will be necessary to establish the TRV based on the MOR Effect Group data and the TRV is equal to the highest NOAEL below the lowest LOAEL for MOR.

If the weighted mean NOAEL is less than the lowest LOAEL for MOR then the mechanism of toxicity of the contaminant is examined. If the mechanism, or mode-of-action of toxicity, is not addressed by the Effect Measures in the GRO, REP and MOR Effect Groups then the TRV is equal to the highest NOAEL below the lowest LOAEL for the appropriate effect group. This possible pathway for TRV derivation is included to allow the toxicologist to set a TRV based on the data most appropriate for the particular contaminant.

If the mechanism of toxicity is addressed by the effect measures in the GRO, REP and MOR groups then the TRV is equal to the Weighted Geometric Mean of the adjusted NOAELs for REP and GRO.

### Step 5: Are there at least 3 LOAELs for GRO & REP?

If there are at least 3 LOAELs for GRO and REP then the TRV is equal to the lowest LOAEL divided by an uncertainty factor. If there are less than 3 LOAELs then the user goes to Step 6.



The uncertainty factor is intended to extrapolate from the LOAEL (lowest observed effect) to a NOAEL (no observed effect) value. In order to derive an UF to approximate the NOAEL from the LOAEL, the LOAEL to NOAEL ratios in the Wildlife TRV database were examined (Table 4.2). To date there are 152 unique paired LOAEL/NOAEL values in the database. Duplicate values (the same ratio for multiple endpoints measured) were removed and the following frequency table constructed:

<b>Table 4.2</b> <b>Frequency of LOAEL to NOAEL Ratios within the</b> <b>Wildlife TRV Database</b>	
<b>Ratio</b>	<b>Number of Cases</b>
1 to 2	88
3 to 5	47
6 to 8	1
9 to 10	12
12 to 14	1
15 to 17	1
18 to 20	0
21 to 30	0
31 to 50	2
Total	152 Cases

Approximately 88% of the LOAEL values are within a factor of 5 of the respective paired NOAEL value (Table 4.2). Approximately 97% of the values are within a factor of 10. As the purpose of the TRV is for calculation of (conservative) soil screening values, a value of 10 was chosen as the UF as in 97% of the cases within the wildlife TRV database, the NOAEL is within a factor of 10 of the LOAEL. This quantitative result is not surprising. Dosing studies are commonly designed with order of magnitude increased in dose (e.g., 1, 10, 100, 1000). Therefore, threshold approaches will consequently most likely end up with a factor of 10 between NOAEL and LOAEL values.

Chapman et al (1998) and e,p&t (1996) criticize the use of the LOAEL in approximating a NOAEL dose. They argue that LOAEL determination is a function of the spacing of dietary concentrations and statistical power of the test and that LOAELs are often incorrectly low due to statistical artifacts and that these uncertainties are compounded when the LOAEL is divided by an uncertainty factor. While it is true that NOAEL and LOAEL determination is function of study design, it is hoped that the NOAEL and LOAEL brackets the threshold. As many LOAELs may be incorrectly low it is assumed that the use of an UF equal to 10 will successfully bracket the lower range of the possible threshold (NOAEL). This UF value will be updated as more toxicological data becomes available within the TRV wildlife

database.

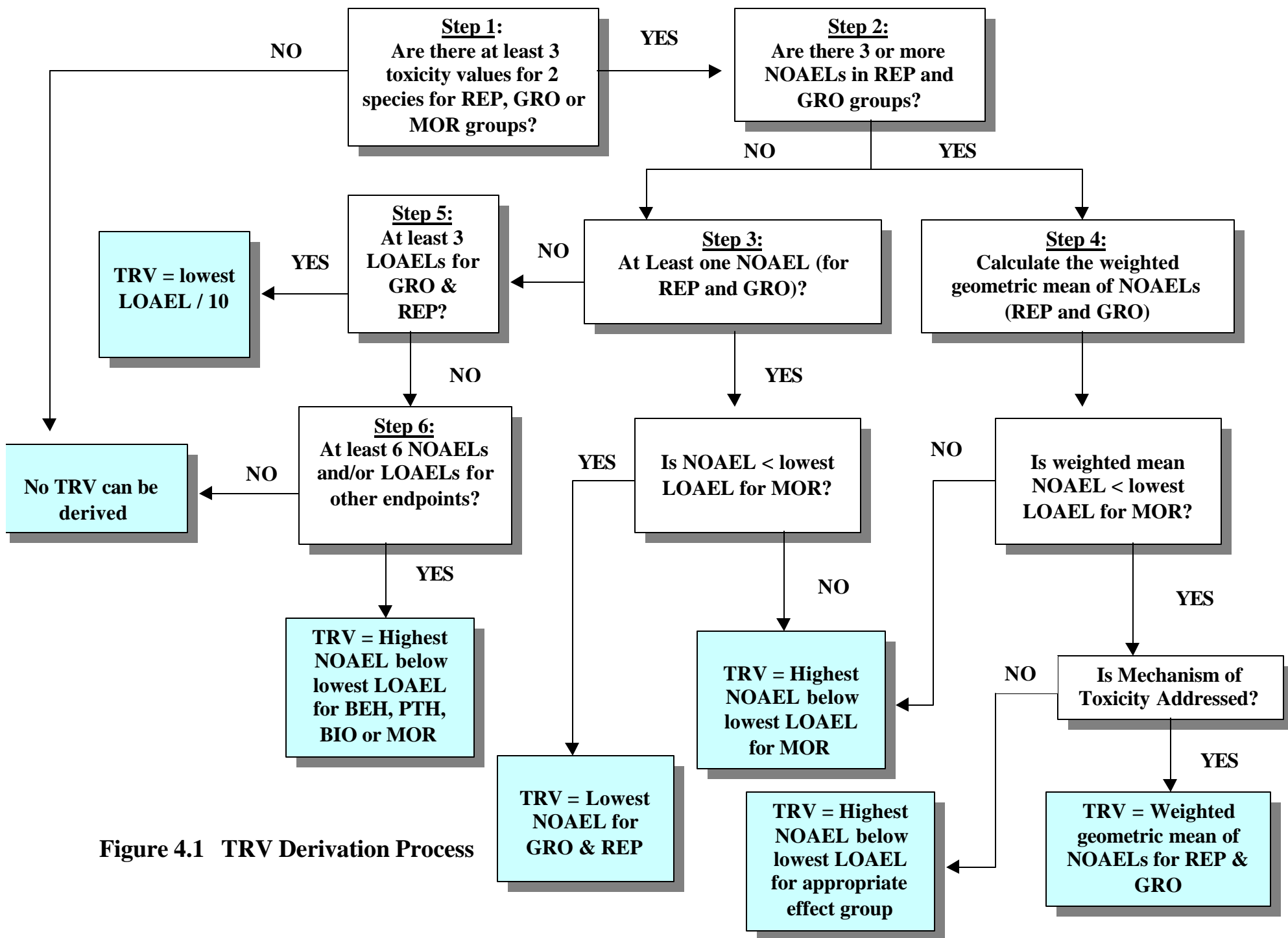
For the contaminants for which TRVs have been derived to date, there has not been an instance where this step was used to derive a TRV. All contaminants examined to date have either had sufficient data to derive a TRV based on NOAEL values or data is not available at all (antimony for birds and RDX for birds).

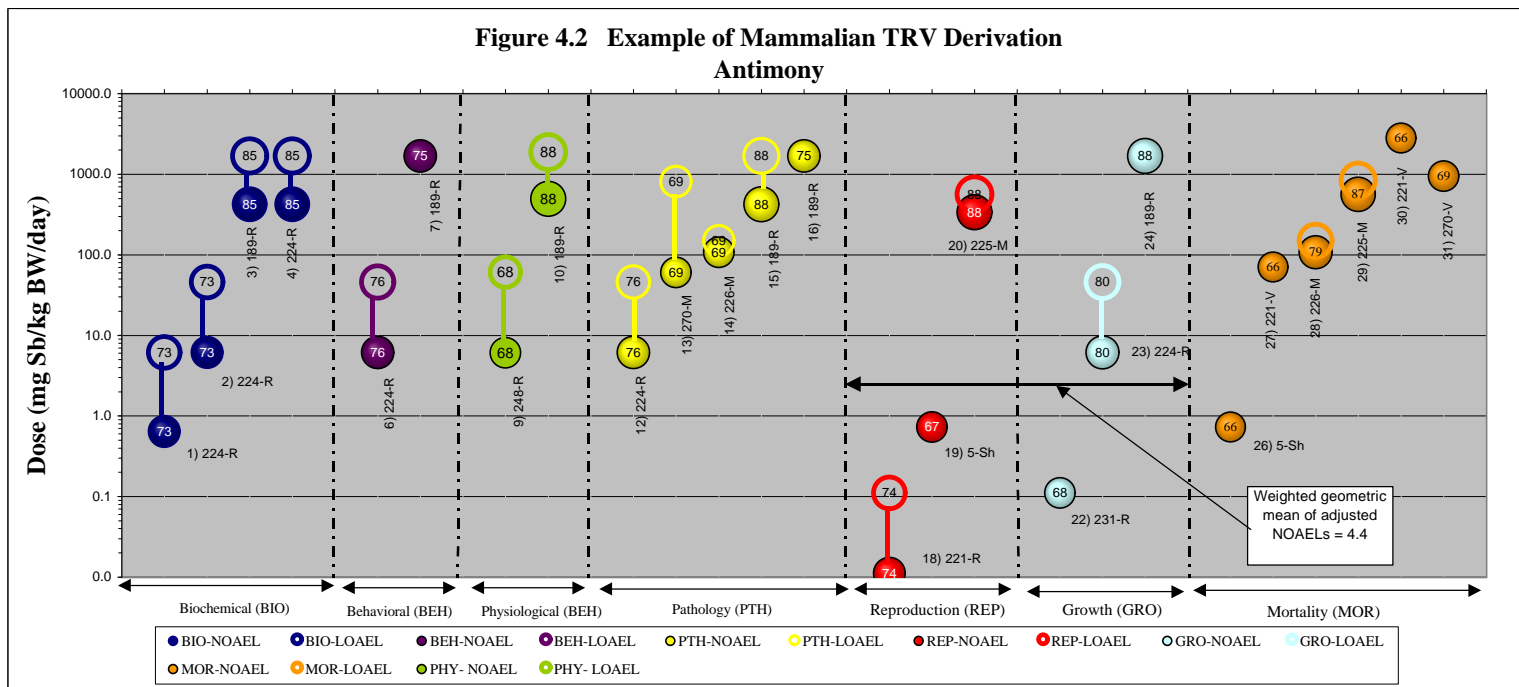
**Step 6: Are there at least 6 LOAEL values available for other endpoints?**

In cases where there are less than three LOAEL values available for GRO or REP Effect groups, the TRV can be derived based on the available LOAEL values for other Effect Groups (BEH, PTH, BIO, PHY, MOR). As this type of dose-response data is considered to be less useful for establishing a TRV twice the number of data points are required as a minimum to derive a TRV (compared to data for GRO, REP and MOR). The highest NOAEL below the lowest LOAEL for each of the Effect Groups (BEH, PTH, PHY, BIO and MOR) are identified and the lowest of these is identified as the TRV. If less than six total NOAEL or LOAEL values are not available then a TRV cannot be derived.

#### **4.6 Examples**

Three examples of TRV derivation are provided as Figures 4.2, 4.3 and 4.4 on the following pages. The TRVs derived to data for the Eco-SSL contaminants are provided as Appendix 4-6.





Result number → 1) 10 - C  
Reference Number → 10 - C  
Test Species → C

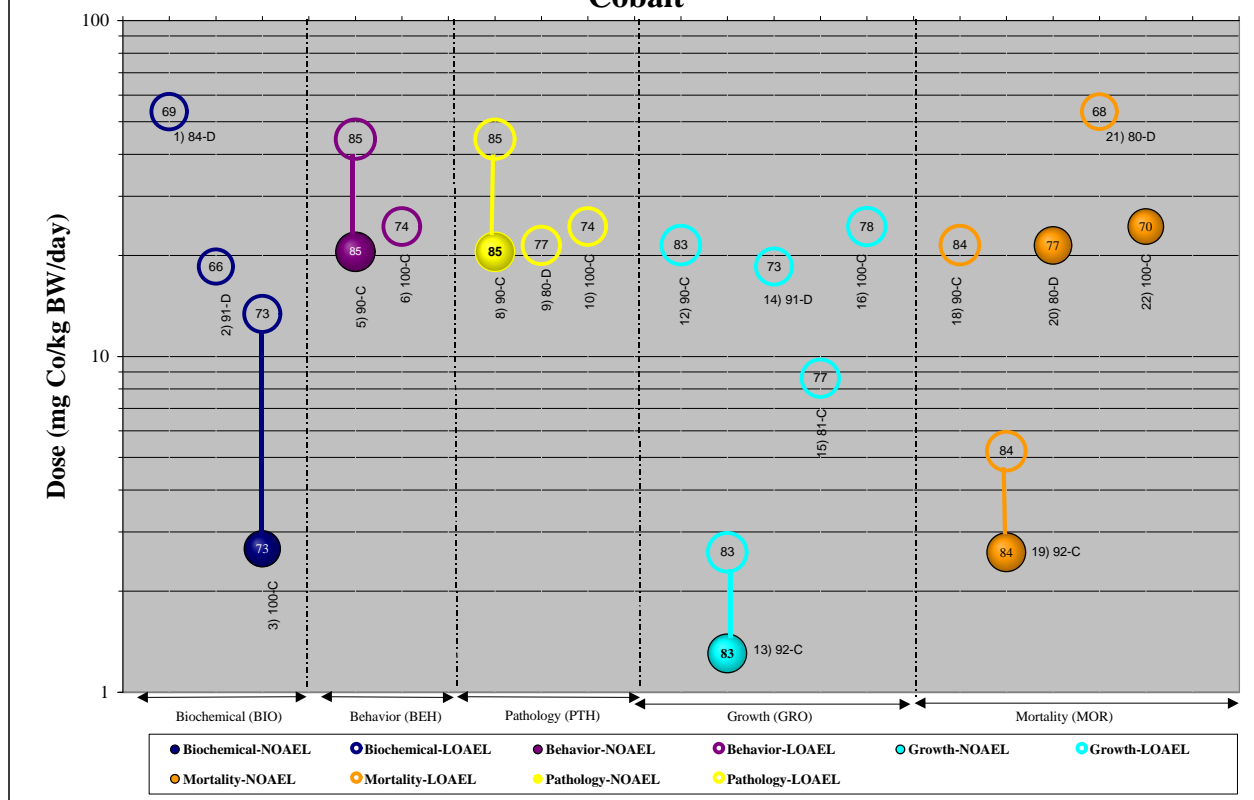
#### Test Species Key

Sh = sheep  
R = rat  
M = mouse  
Pg = pig  
V = vole

#### Wildlife TRV Derivation Process

- 1) There are at least three results available for two test species within the GRO, REP and MOR effect groups. There is enough data to derive TRV.
- 2) There are at least three NOAEL results available for calculation of a weighted geometric mean.
- 3) The weighted geometric mean of the adjusted NOAEL values for GRO and REP equals 4.4 mg Sb/kg BW/day.
- 4) The weighted geometric mean NOAEL is lower than the lowest LOAEL for mortality.
- 5) The mammalian wildlife TRV for antimony is equal to the 4.4 mg Sb/kg BW/day.

**Figure 4.3 Example of Avian TRV Derivation  
Cobalt**

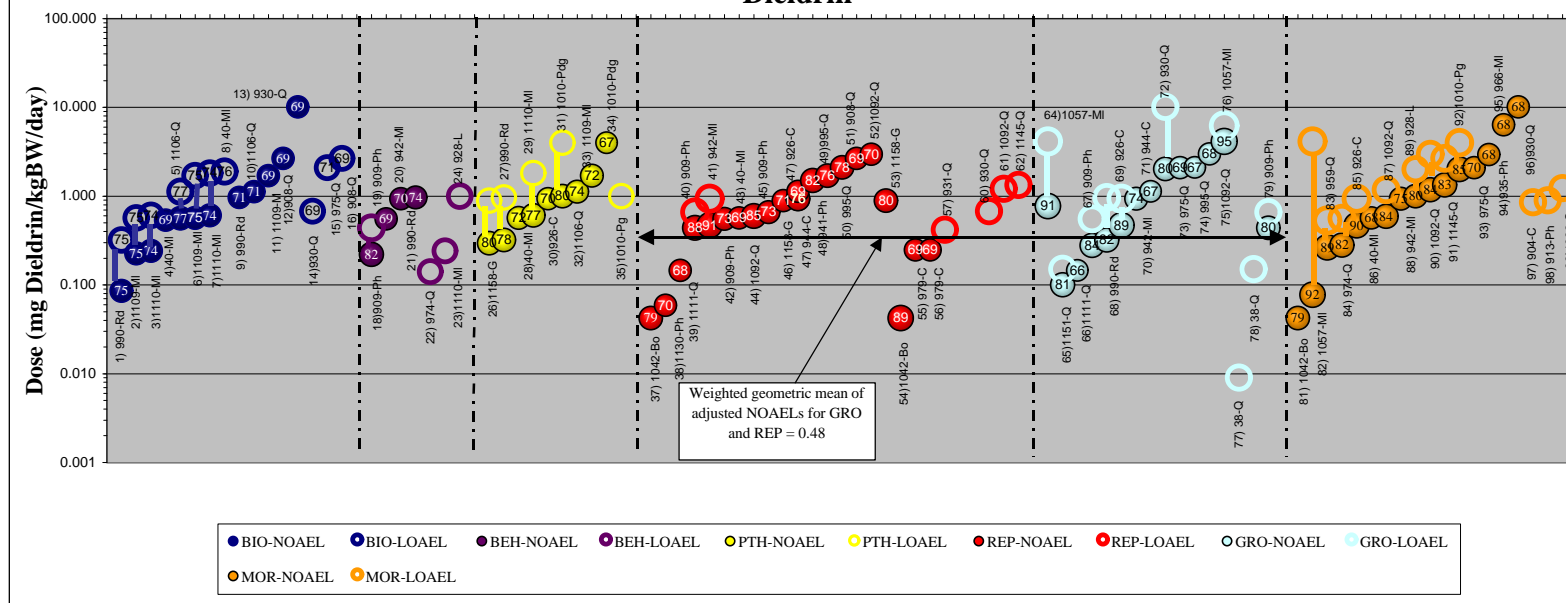


Result number → 1) 10 - C  
Reference Number →  
Test Species →

#### Wildlife TRV Derivation Process

- 1) There are at least three results available for two test species within the GRO, REP and MOR effect groups.  
There is enough data to derive TRV.
- 2) There are less than three NOAEL results available within either the GRO, REP or MOR effect groups.  
A weighted geometric mean cannot be calculated.
- 3) There is at least one NOAEL result available for growth (GRO)
- 4) The NOAEL for growth at 1.3 mg Co/kg BW/day is less than the lowest LOAEL for mortality.
- 5) The NOAEL of 1.3 mg Co/kg BW/day is the avian TRV for cobalt.

**Figure 4.4 Example of Avian TRV Derivation**  
**Dieldrin**



Result number → 1) 10 - C  
Reference Number → Test Species

**Test Species Key**

MI = mallard	Ph = pheasant	G = guinea fowl
Q = quail	L = loggerhead shrike	C = chicken
Rd = ring dove	Bo = barn owl	Pdg = pigeon

### Wildlife TRV Derivation Process

- 1) There are at least three results available for two test species within the GRO, REP and MOR effect groups.
- 2) There are three NOAEL results available for calculation of a weighted geometric mean.
- 3) The weighted geometric mean of the adjusted NOAELs for REP and GRO results equals 0.48 mg dieldrin/kg BW/day.
- 4) The weighted geometric mean NOAEL is less than the lowest LOAEL for mortality.
- 5) The avian wildlife TRV for dieldrin is equal to 0.48 mg dieldrin/kg BW/day

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## Appendix 4-6

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# Ecological Soil Screening Level Guidance - Draft

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*Wildlife TRVs*

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*July 3, 2000*

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**Appendix 4-6**

**Wildlife Toxicity Reference Values**

**for**

**Ecological Soil Screening Levels (Eco-SSLs)**

July 3, 2000



**Prepared for USEPA Region 8**

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## 1.0 INTRODUCTION

The United States Environmental Protection Agency (USEPA) Office of Emergency and Remedial Response (OERR) with a multi-stakeholder workgroup developed risk-based based soil screening levels (Eco-SSLs). Eco-SSLs are concentrations of contaminants in soils that are protective of ecological receptors that commonly come into contact with soil or ingest biota that live in or on soil. Eco-SSLs are derived separately for four groups of ecological receptors: mammals, birds, plants, and soil invertebrates.

The Eco-SSLs are used in the ERA process to identify the contaminants that need to be evaluated further in the characterization of exposure, effects and risk characterization. The Eco-SSLs are used during Step 2 of the Superfund ERA process, the screening-level risk calculation. This step normally is completed at a time when limited soil concentration data are available, and other site-specific data (e.g., contaminant bioavailability information, area use factors) are not available. It is expected that the Eco-SSLs will be used to screen the site soil data to identify those contaminants that are not of potential ecological concern and do not need to be considered in the subsequent baseline ERA.

Plant and soil invertebrate Eco-SSLs were derived from available plant and soil invertebrate toxicity data. The mammalian and avian Eco-SSLs were the result of back-calculations from a Hazard Quotient (HQ) of 1.0. The HQ is equal to the dose (associated with the contaminant concentration in soil) divided by a toxicity reference value (TRV). Generic food chain models were used to estimate the relationship between the concentration of the contaminant in soil and the dose for the receptor (mg per kg body weight per day). The TRV represents a numerical estimate of a no adverse level (dose) for the respective contaminant.

The procedure(s) for deriving the mammalian and avian oral TRVs needed for calculation of Eco-SSLs for mammals and birds are contained within four standard operating procedures (SOPs):

- |        |  |
|--------|--|
| SOP #1 | Literature Search and Retrieval (Exhibit 4-1)                |
| SOP #2 | Literature Review, Data Extraction and Coding (Appendix 4-3) |
| SOP #3 | Data Evaluation (Exhibit 4-4)                                |
| SOP #4 | Derivation of the Oral TRV (Appendix 4-5)                    |

This document serves to report the results of the wildlife TRV derivation process for the 22 Eco-SSL contaminants. The wildlife TRVs are derived using the results extracted from the toxicological data identified in SOP#1 using, in part, the data evaluation scores for each result applied as described in SOP #3. The results are reported separately by contaminant.



## **2.0 ANTIMONY**

### **2.1 Literature Search, Retrieval and Review**

The electronic literature search for antimony toxicity data was completed according to the procedures provided in Exhibit 4-1. The search results are reported as four separate lists. The first list contains studies identified during the electronic search that were rejected for use based on a review of the abstract and title. The second list reports the literature for which useful toxicological data was identified and extracted (literature coded). The third list reports the literature that was retrieved, reviewed and then rejected (literature rejected). The fourth list contains literature identified in the search that either could not be retrieved for review or has not been received for review (literature pending). These references are listed as Section 2.5.

Each of the citations in these lists are identified with a unique record number assigned as part of the data extraction process as described in Appendix 4-3 (SOP #2). Citations on the “literature not coded” list are labeled with respective literature rejection criteria also described in Appendix 4-3 (SOP #2).

### **2.2 Data Review and Evaluation**

#### ***Avian Data***

The literature search process (Exhibit 4-1) did not identify any acceptable studies for antimony and birds.

#### ***Mammalian Data***

Forty-six studies were identified for antimony and mammals. Of these, 34 were rejected and one could not be located for retrieval. Data was extracted from the remaining eleven studies for derivation of the TRV. The data reviewed and extracted from these studies is summarized in Table 2.1.

### **2.3 Mammalian Antimony TRV**

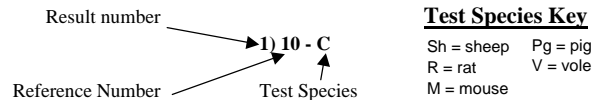
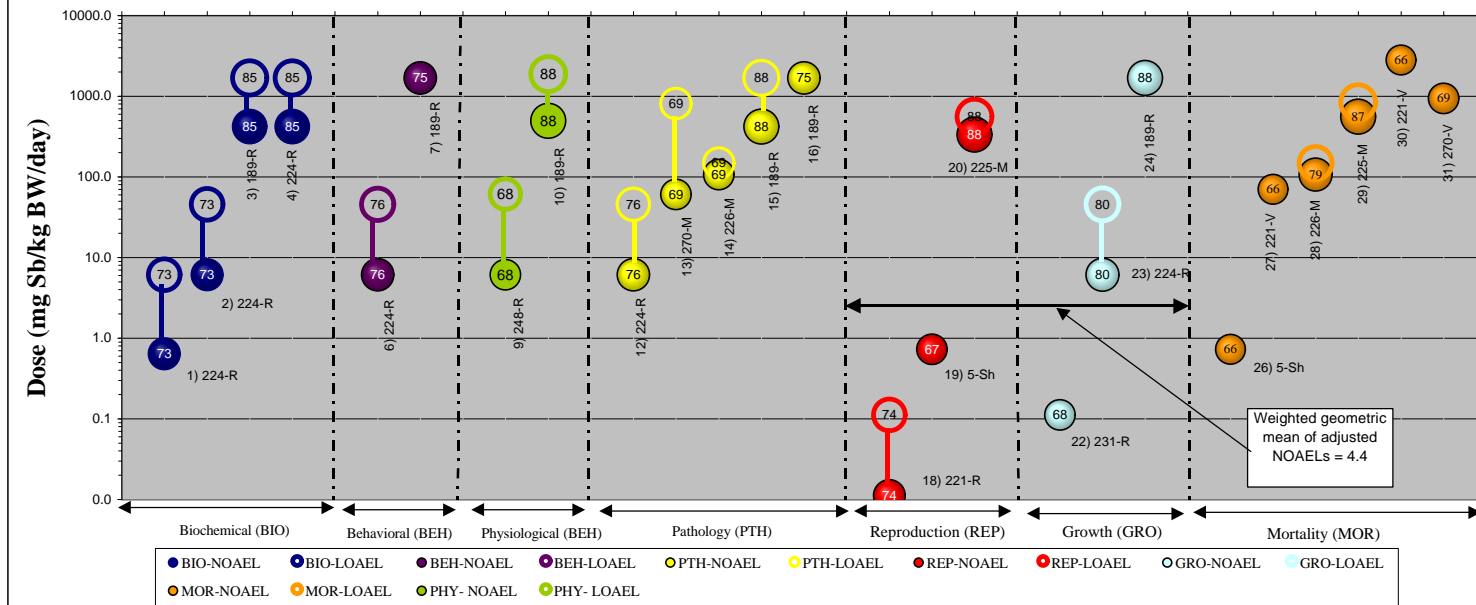
The NOAEL and LOAEL values for results with data evaluation scores above 65 are plotted on Figure 2.1. The following steps were completed to identify a TRV.

- 1) There are at least three results available for growth (GRO), reproduction (REP) or mortality (MOR) endpoints for at least two test species. There is enough data to derive a TRV.
- 2) There are at least three NOAEL results available for GRO or REP to calculate a weighted geometric mean.

**Table 2.1**  
**Mammalian Toxicity Data For Antimony**

TEST INFORMATION			EXPOSURE INFORMATION											EFFECTS INFORMATION						DATA EVALUATION SCORES												
Result #	Test ID	Contaminant Form	Species	# of Conc/ Doses	Conc/Dose Units	Method of Analyses	Route of Exposure	Exposure Duration	Duration Units	Age	Age Units	Lifestage	Sex	General Effect Group	Effect Type	Effect Measure	Response Site	NOAEL Dose (mg/kg/day)	LOAEL Dose (mg/kg/day)	Data Source	Dose Route	Test Substrate	Contaminant form	Dose Quantification	Endpoint	Dose Range	Statistical Power	Exposure Duration	Test Conditions	Total		
1	224-Sb-Poon -ML-FD-1-BIO-1	Antimony potassium tartrate	rat	5	mg Sb/kg BW/day	M	DR	13	w	NR	NR	NR	F	BIO	CHM	GLUC	WO	0.64	6.1	10	5	10	5	10	1	8	10	10	4	73		
2	224-Sb-Poon -ML-FD-1-BIO-2	Antimony potassium tartrate	rat	5	mg Sb/kg BW/day	M	DR	13	w	NR	NR	NR	F	BIO	ENZ	ALPH	WO	6.1	46	10	5	10	5	10	1	8	10	10	4	73		
3	189-Sb-Hext -ML-FD-1-BIO-1	Antimony trioxide	rat	4	mg Sb/kg BW/day	M	FD	90	d	NR	NR	AD	M	BIO	CHM	TRIG	BL	421	1686	10	10	10	10	10	1	8	10	6	10	85		
4	189-Sb-Hext -ML-FD-1-BIO-2	Antimony trioxide	rat	4	mg Sb/kg BW/day	M	FD	90	d	NR	NR	AD	M	BIO	ENZ	ALPH	BL	421	1686	10	10	10	10	10	1	8	10	6	10	85		
5																																
6	224-Sb-Poon -ML-FD-1-BEH-3	Antimony potassium tartrate	rat	5	mg Sb/kg BW/day	M	DR	13	w	NR	NR	NR	F	BEH	FDB	WCONS	WO	6.1	46	10	5	10	5	10	4	8	10	10	4	76		
7	189-Sb-Hext -ML-FD-1-BEH-3	Antimony trioxide	rat	4	mg Sb/kg BW/day	M	FD	90	d	NR	NR	AD	M	BEH	FDB	FCNS	WO	1686		10	10	10	10	10	4	4	1	6	10	75		
8																																
9	248-Sb-Marmo-ML-DR-1-PHY-1	Antimony chloride	rat	3	mg%	U	DR	22	d	NR	NR	AD	BH	PHY	PHY	VASO	WO	6.1	61	10	5	5	10	6	4	8	10	6	4	68		
10	189-Sb-Hext -ML-FD-1-PHY-4	Antimony trioxide	rat	4	mg Sb/kg BW/day	M	FD	90	d	NR	NR	AD	F	PHY	PHY	EXCR	WO	494	1879	10	10	10	10	10	4	8	10	6	10	88		
11																																
12	224-Sb-Poon -ML-FD-1-PTH-4	Antimony potassium tartrate	rat	5	mg Sb/kg BW/day	M	DR	13	w	NR	NR	NR	F	PTH	HIS	FIBR	WO	6.1	46	10	5	10	5	10	4	8	10	10	4	76		
13	270-Sb-Ainsw-ML-FD-1-PTH-2	Antimony trioxide	mouse	3	mg/kg diet	U	FD	18	d	NR	NR	NR	NR	PTH	ORWT	ORWT	KI	60	810	10	10	5	10	6	4	4	10	6	4	69		
14	226-Sb-Diete-ML-DR-1-PTH-1	Antimony potassium tartrate	mouse	6	mg/kg BW/day	U	DR	14	d	6	w	NR	F	PTH	HIS	GSLN	WO	107	148	10	5	5	5	10	4	10	10	6	4	69		
15	189-Sb-Hext -ML-FD-1-PTH-5	Antimony trioxide	rat	4	mg Sb/kg BW/day	M	FD	90	d	NR	NR	AD	M	PTH	ORWT	ORWT	LI	421	1686	10	10	10	10	10	4	8	10	6	10	88		
16	189-Sb-Hext -ML-FD-1-PTH-6	Antimony trioxide	rat	4	mg Sb/kg BW/day	M	FD	90	d	NR	NR	AD	M	PTH	HIS	GHIS	LI	1686		10	10	10	10	10	4	4	1	6	10	75		
17																																
18	231-Sb-Rossi-ML-DR-1-REP-2	Antimony trichloride	rat	3	mg/dl	U	DR	38	d	22	F	NR	M	REP	REP	PRWT	WO	0.01	0.1	10	5	5	10	6	10	8	10	6	4	74		
19	5-Sb-James-ML-OR-1-REP-1	Antimony potassium tartrate	sheep	2	mg/kg BW/day	U	OR	155	d	1	y	NR	F	REP	REP	PROG	WO	0.73		10	8	5	5	10	10	4	1	10	4	67		
20	225-Sb-Gurna-ML-GV-1-REP-1	Antimony trioxide	mouse	4	mg/kg BW/day	M	GV	21	d	8	w		M	REP	REP	SPCV	WO	335	559	10	8	10	10	10	10	10	10	6	4	88		
21																																
22	231-Sb-Rossi-ML-DR-1-GRO-3	Antimony trichloride	rat	3	mg/dl	U	DR	38	d	22	F	NR	M	GRO	GRO	BDWT	WO	0.11		10	5	5	10	6	8	4	10	6	4	68		
23	224-Sb-Poon -ML-FD-1-GRO-5	Antimony potassium tartrate	rat	5	mg Sb/kg BW/day	M	DR	13	w	NR	NR	NR	F	GRO	GRO	BDWT	WO	6.1	46	10	5	10	5	10	8	8	10	10	4	80		
24	189-Sb-Hext -ML-FD-1-GRO-7	Antimony trioxide	rat	4	mg Sb/kg BW/day	M	FD	90	d	NR	NR	AD	M	GRO	GRO	BDWT	WO	1686		10	10	10	10	10	8	4	10	6	10	88		
25																																
26	5-Sb-James-ML-OR-1-MOR-2	Antimony potassium tartrate	sheep	2	mg/kg BW/day	U	OR	155	d	1	y	NR	F	MOR	MOR	MORT	WO	0.7		10	8	5	5	10	9	4	1	10	4	66		
27	221-Sb-Ainsw-ML-FD-1-MOR-3	Antimony trioxide	vole	2	mg Sb/kg diet	U	FD	60	d	35	d	NR	M	MOR	MOR	MORT	WO	70		10	10	5	10	7	9	4	1	6	4	66		
28	226-Sb-Diete-ML-DR-1-MOR-2	Antimony potassium tartrate	mouse	6	mg/kg BW/day	M	DR	14	d	6	w	NR	F	MOR	MOR	MORT	WO	107	148	10	5	10	5	10	9	10	10	6	4	79		
29	225-Sb-Gurna-ML-GV-1-MOR-3	Antimony trioxide	mouse	4	mg/kg BW/day	M	GV	21	d	8	w	NR	M	MOR	MOR	MORT	WO	559	839	10	8	10	10	10	9	10	10	6	4	87		
30	221-Sb-Ainsw-ML-FD-2-MOR-1	Antimony trioxide	vole	3	mg Sb/kg diet	U	FD	12	d	35	d	NR	M	MOR	MOR	MORT	WO	2812		10	10	5	10	7	9	4	1	6	4	66		
31	270-Sb-Ainsw-ML-FD-2-MOR-1	Antimony trioxide	vole	3	mg/kg diet	U	FD	21	d	NR	NR	NR	NR	MOR	MOR	MORT	WO	942		10	10	5	10	10	9	4	1	6	4	66		

**Figure 2.1 Mammalian TRV Derivation for Antimony**



#### Wildlife TRV Derivation Process

- 1) There are at least three results available for two test species within the GRO, REP and MOR effect groups. There is enough data to derive TRV.
- 2) There are at least three NOAEL results available for calculation of a weighted geometric mean.
- 3) The weighted geometric mean of the adjusted NOAEL values for GRO and REP equals 4.4 mg Sb/kg BW/day.
- 4) The weighted geometric mean NOAEL is lower than the lowest LOAEL for mortality.
- 5) The mammalian wildlife TRV for antimony is equal to the 4.4 mg Sb /kg BW/day.

- 3) The NOAEL values are first adjusted based on their respective data evaluation score.

$$\text{Adjusted NOAEL} = \text{NOAEL} * (\text{Data Evaluation Score} / 100)$$

- 4) The weighted geometric mean of the adjusted NOAEL values is calculated as presented in Table 2.1 and is equal to:

$$\log(\text{GeoMean}) = \{ \text{score}(1) * \log(\text{adj. NOAEL}(1)) + \dots + \text{score}(n) * \log(\text{adj. NOAEL}(n)) \} / \{ \text{sum of scores} \}$$

<b>Table 2.2</b>					
<b>Mammalian TRV Derivation for Antimony Weighted Geometric Mean of Adjusted NOAELs</b>					
<b>Test ID</b>	<b>NOAELs</b>	<b>Scores</b>	<b>Adjusted NOAEL Value</b>	<b>Weight</b>	<b>Weight*Log Adj NOAEL</b>
231-Sb-Rossi-ML-DR-1-REP-2	0.011	74	0.008	74	-154.29
5-Sb-James-ML-OR-1-REP-1	0.73	67	0.5	67	-20.84
225-Sb-Gurna-ML-GV-1-REP-1	335	88	295	88	217.36
231-Sb-Rossi-ML-DR-1-GRO-3	0.11	68	0.1	68	-76.28
224-Sb-Poon -ML-FD-1-GRO-5	6.13	80	4.9	80	55.24
189-Sb-Hext -ML-FD-1-GRO-7	1686	88	1484	88	279.08
Sum				465	300.28
(Sum of weight*log (adj NOAEL) / Sum of Weights					0.6458
Weighted Geometric Mean					4.4

- 5) The weighted geometric mean NOAEL is lower than the lowest LOAEL for mortality.
- 6) The mammalian wildlife TRV for antimony is equal to the 4.4 mg Sb /kg BW/day.

## **2.4 Avian Antimony TRV**

The literature search did not identify any toxicity studies for antimony and birds that passed the literature exclusion criteria (Chapter 4). An avian TRV for antimony could not be derived.

## **2.5 Antimony Wildlife TRV References**

### ***Antimony Literature Used for TRV Derivation***

**221** Ainsworth, N., Cooke, J. A., and Johnson, M. S. 1991. Behavior and toxicity of antimony in the short-tailed field vole (*Microtus agrestis*). *Ecotoxicol. Environ. Saf.* 21(2):165-170.

**270** Ainsworth, N., Cooke, J. A., and Johnson, M. S. 1991. Biological significance of antimony in contaminated grassland. *Water Air Soil Pollut.* 57-58:193-197.

**226** Dieter, M. P., Jameson, C. W., Elwell, M. R., Lodge, J. W., Hejtmancik, M., Grumbein, S. L., Ryan, M., and Peters, A. C. 1991. Comparative toxicity and tissue distribution of antimony potassium tartrate in rats and mice

dosed by drinking water or intraperitoneal injection. J Toxicol Environ Health 34(1):51-82.

**225** Gurnani, N., Sharma, A., and Talukder, G. 1993. Comparison of clastogenic effects of antimony and bismuth as trioxides on mice in vivo. Biol Trace Elem Res 37(2-3):281-292.

**189** Hext, P. M., Pinto, P. J., and Rimmel, B. A. 1999. Subchronic feeding study of antimony trioxide in rats J.Appl.Toxicol. 19(3):205-209.

**5** James, L. F., Lazar, V. A., and Binns, W. 1966. Effects of sublethal doses of certain minerals on pregnant ewes and fetal development Am J Vet Res 27(116):132-135.

**3701** Kanisawa, M. and Schroeder, H. A. 1969. Life term studies on the effect of trace elements on spontaneous tumors in mice and rats. Cancer Res. 29(4):892-895.

**248** MARMO, E., MATERA, M. G., ACAMPORA, R., VACCA, C., DE SANTIS D, MAIONE, S., SUSANNA, V., CHIEPPA, S., GUARINO, V. and others. 1987. Prenatal and postnatal metal exposure: effect on vasomotor reactivity development of pups. Experimental research with antimony trichloride, thallium sulfate, and sodium metavanadate Curr Ther Res Clin Exp 42(5):823-838.

**224** Poon, R., Chu, I., Lecavalier, P., Valli, V. E., Foster, W., Gupta, S., and Thomas, B. 1998. Effects of antimony on rats following 90-day exposure via drinking water. Food Chem Toxicol 36(1):21-35.

**231** Rossi, F., Acampora, R., Vacca, C., Maione, S., Matera, M. G., Servodio, R., and Marmo, E. 1987. Prenatal and postnatal antimony exposure in rats: effect on vasomotor reactivity development of pups. Teratog Carcinog Mutagen 7(5):491-496.

**267** Schroeder, H. A. 1970. Metallic Micronutrients and Intermediary Metabolism: Progress rept. no. 3 (Final). 22 p.

### ***Antimony Literature Rejected***

**253** **Diss** Ainsworth, N. 1988. Distribution and biological effects of antimony in contaminated grasslands.:325.

**263** **Bio Acc** Ainsworth, N., Cooke, J. A., and Johnson, M. S. 1990. Distribution of antimony in contaminated grassland. 2. Small mammals and invertebrates. Environ. Pollut. 65(1):79-87.

**227** **No Oral** al Khawajah, A., Larbi, E. B., Jain, S., al-Gindan, Y., and Abahussain, A. 1992. Subacute toxicity of pentavalent antimony compounds in rats. Hum Exp Toxicol 11(4):283-288.

**272** **Rev** ATSDR. 1992. Toxicological Profile for Antimony.

**3776** **No Oral** Baetjer, A. M. 1969. Effects of dehydration and environmental temperature on antimony toxicity. Arch. Environ. Health 19(6):784-792.

**3777** **No Oral** Bradley, W. R. and Fredrick, W. G. 1941. Toxicity of antimony-animal studies. Ind. Med. 2:15.

**220** **Lead Shot** Damron, B. L. and Wilson, H. R. 1975. Lead toxicity of bobwhite quail. Bull Environ Contam Toxicol 14(4):489-9.

**3780** **Dup** Dieter, M. P. 1992. NTP report on the toxicity studies of antimony potassium tartrate in F344/N rats and B6C3F1 mice (drinking water and intraperitoneal injection studies). National Toxicology Program. NIH

- 258 FL** Erusalimskii, E. I. 1973. Effect of antimony trioxide and urethane on the weight and peripheral blood of mice *Vopr. Klin. Eksp. Onkol.* 9:214-19.
- 262 FL** Filippelli, A., Marrazzo, R., Angrisani, M., Filippelli, W., and Rossi, F. 1992. Vasomotor reactivity in rats exposed pre- and postnatally to toxic agents and drugs. *Sibirskii Biologicheskii Zhurnal*:32-44.
- 188 Rev** Gebel, T. 1997. Arsenic and antimony: comparative approach on mechanistic toxicology *Chem.Biol.Interact.* 107(3):131-144.
- 3778 No Oral** Goodwin, L. G. 1944. The toxicity and trypanocidal activity of some organic antimonials. *J. Pharmacol.* 81:224.
- 271 No oral** Groth, D. H., Stettler, L. E., and Burg, J. R. 1986. Carcinogenic effects of antimony trioxide and antimony ore concentrate in rats *J Toxicol Environ Health* 18:607-626.
- 246 Gene** Gurnani, N., Sharma, A., and Talukder, G. 1994. Comparison of the clastogenic effects of antimony trioxide on mice in vivo following acute and chronic exposure. *Biometals* 5(1):47-50.
- 240 Bio Acc** HENNY, C. J., BLUS, L. J., THOMPSON, S. P., and WILSON, U. W. 1989. Environmental contaminants, human disturbance and nesting of double-crested cormorants in northwestern Washington (USA). *COLON WATERBIRDS* 12(2):198-206.
- 254 FL** Hiraoka, Norio. 1986. The toxicity and organ distribution of antimony after chronic administration to rats *Kyoto-furitsu Ika Daigaku Zasshi*, V95, N8, P997-1017
- 301 No Oral** Hoshishima, K. 1983. 'Play' behavior and trace dose of metal(s) in mice *Dev. Toxicol. Environ. Sci.* 11:525-528.
- 235 Rev** Liepins, R. and Pearce, E. M. 1976. Chemistry and toxicity of flame retardants for plastics. *Environ Health Perspect* 17:55-63.
- 190 Rev** Lynch, B. S., Capen, C. C., Nestmann, E. R., Veenstra, G., and Deyo, J. A. 1999. Review of subchronic/chronic toxicity of antimony potassium tartrate *Regul.Toxicol.Pharmacol.* 30(1):9-17.
- 260 No Dose** Malzahn, E. 1983. Post natal changes in trace elements and in oxidation reduction activity in laboratory bank voles *clethrionomys-glareolus* *Acta Theriol* 28(1-8):33-54.
- 261 Bio Acc** Malzahn, E. 1981. Trace elements and their significance in the post natal development of seasonal generations of the bank vole *clethrionomys-glareolus* *Acta Theriol* 26(8-15):231-256.
- 237 Bio Acc** Molokhia, M. M. and Smith, H. 1969. The behaviour of antimony in blood. *J Trop Med Hyg* 72(9):222-5.
- 266 Rev** NAS, Subcommittee on Mineral Toxicity Committee on Animal Nutrition. 1980. Mineral Tolerance of Domestic Animals. National Research Council (NRC): United States. 588.
- 191 Rev** Oskarsson, A. and Fowler, B. A. 1987. Alterations in renal heme biosynthesis during metal nephrotoxicity *Ann.N.Y.Acad.Sci.* 514:268-277.
- 219 Lead Shot** Pain, D. J., Amiard-Triquet, C., and Sylvestre, C. 1992. Tissue lead concentrations and shot

ingestion in nine species of waterbirds from the Camargue (France). *Ecotoxicol Environ Saf* 24(2):217-33.

**3779 Acu** Pribyl, E. 1927. Nitrogen metabolism in experimental subacute arsenic and antimony poisoning. *J. Biol. Chem.* 74:775.

**45 No Oral** Ridgway, L. P. and Karnofsky, D. A. 1952. The effects of metals on the chick embryo: toxicity and production of abnormalities in development *Ann N Y Acad Sci* 55:203-215.

**243 Rev** Schardein, J. L., Keller, K. A., and Schwetz, B. A. 1989. Potential human developmental toxicants and the role of animal testing in their identification and characterization *Crit Rev Toxicol* 19(3):251-339.

**238 Mix** Schroeder, H. A., Mitchener, M., Balassa, J. J., Kanisawa, M., and Nason, A. P. 1968. Zirconium, niobium, antimony and fluorine in mice: effects on growth, survival and tissue levels. *J Nutr* 95(1):95-101.

**252 Mix** Schroeder, H. A., Mitchener, M., and Nason, A. P. 1970. Zirconium, niobium, antimony, vanadium and lead in rats: life term studies. *J Nutr* 100(1):59-68.

**3771 Rev** Smyth Jr., H. F. and Carpenter, C. P. 1948. Further experience with the range finding test in the industrial toxicology laboratory. *J. Ind. Hyg. Toxicol.* 30(1):63-68.

**118 No Oral** Tsujii, H. and Hoshishima, K. 1979. Effect of the administration of trace amounts of metals to pregnant mice upon the behavior and learning of their offspring *SHINSHU DAIGAKU NOGAKUBU KIYO(J FAC AGRIC SHINSHU UNIV)* 16:13-28.

**273 Rev** USEPA. 1992. Drinking Water Criteria Document for Antimony. USEPA Health and Ecological Criteria Division, Office of Science and Technology, Office of Water.

**3772 Rev** Venugopal, D. and T. D. Luckey, Eds. 1978. Antimony (Sb). In: Venugopal, D. and T. D. Luckey, Eds. *Metal Toxicity in Mammals - Vol 2. Chemical Toxicity of Metals and Metalloids.* Plenum: New York, NY. 213-216.

### ***Antimony Literature Pending***

**244** USEPA UNIV OF PITTSBURGH. The single dose and subacute toxicity of antimony oxide (Sb<sub>2</sub>O<sub>3</sub>) with cover letter EPA/OTS; Doc #878210812 1983.

### **3.0 CHROMIUM**

#### **3.1 Literature Search, Retrieval and Review**

The electronic literature search for chromium toxicity data was completed according to the procedures provided in Exhibit 4-1. The search results are reported as four separate lists. The first list contains studies identified during the electronic search that were rejected for use based on a review of the abstract and title. The second list reports the literature for which useful toxicological data was identified and extracted (literature coded). The third list reports the literature that was retrieved, reviewed and then rejected (literature rejected). The fourth list contains literature identified in the search that either could not be retrieved for review or has not been received for review (literature pending). These references are listed as Section 3.5.

Each of the citations in these lists are identified with a unique record number assigned as part of the data extraction process as described in Appendix 4-3 (SOP #2). Citations on the “literature not coded” list are labeled with respective literature rejection criteria also described in Appendix 4-3 (SOP #2).

#### **3.2 Data Review and Evaluation**

The electronic and manual literature search process (Exhibit 4-1) for chromium identified 113 studies. Of these, 27 studies contained data used to derive either the mammalian or avian TRVs for the Eco-SSL. Sixty-three studies were rejected for use and 22 are pending either receipt or review.

##### ***Mammalian Data***

Data was extracted from nine studies for derivation of the mammalian TRV for trivalent chromium and 20 studies for hexavalent chromium. The data reviewed and extracted from these studies is summarized in Table 3.1 and 3.2, respectively, for trivalent and hexavalent chromium..

##### ***Avian Data***

Data was extracted from three studies for derivation of the avian trivalent chromium TRV. The data reviewed and extracted from these studies is summarized in Table 3.3. There were only two studies that passed the literature rejection criteria for use in establishing an avian TRV for hexavalent chromium. Both of these studies report results for the chicken thus the minimum data set required for TRV derivation (at least two species) is not available. An avian TRV for hexavalent chromium could not be derived.



Table 3.1 Mammalian Toxicity Data for Trivalent Chromium

TEST INFORMATION				EXPOSURE INFORMATION											DATA EVALUATION SCORES																
Result #	Reference Number	Test ID	Chemical Form	Species	# of Conc/ Doses	Reported Conc/Dose Units	Method of Analyses	Route of Exposure	Exposure Duration	Duration Units	Age	Age Units	Lifestage	Sex	General Effect Group	Effect Type	Effect Measure	Response Site	NOAEL Dose (mg/kg/day)	LOAEL Dose (mg/kg/day)	Data Source	Dose Route	Test Substance	Chemical form	Dose Quantification	Endpoint	Dose Range	Statistical Power	Exposure Duration	Test Conditions	Total
1	3729	3729-Cr-Ivank-ML-FD-1-BIO-4	Cr <sub>2</sub> O <sub>3</sub>	rat	3	g Cr <sub>2</sub> O <sub>3</sub> /kg BW	U	FD	90	d	100	d	MA	F	BIO	CHM	HMGL	WO	547		10	10	5	10	10	1	4	10	10	4	74
2	3061	3061-Cr-Meena-ML-GV-2-BIO-2	Chromic chloride	rat	1	mg Cr/kg BW/ day	M	GV	60	d	NR	NR	NR	M	BIO	BIO	GLUC	BL		10	10	8	10	10	10	1	4	10	10	4	77
3	3061	3061-Cr-Meena-ML-GV-2-BIO-4	Chromic chloride	rat	1	mg Cr/kg BW/ day	M	GV	60	d	NR	NR	NR	M	BIO	ENZ	OTHR	BL		10	10	8	10	10	10	1	4	10	10	4	77
4																															
5	3729	3729-Cr-Ivank-ML-FD-1-BEH-2	Cr <sub>2</sub> O <sub>3</sub>	rat	3	g Cr <sub>2</sub> O <sub>3</sub> /kg BW	U	FD	90	d	100	d	MA	F	BEH	FDB	FCNS	WO	547		10	10	5	10	10	4	4	1	10	4	68
6	3009	3009-Cr-Batai-ML-DR-2-BEH-2	Chromium Chloride	rat	2	ppm	U	DR	12	w	NR	NR	MA	M	BEH	BEH	OTHR	WO		36	10	5	5	10	6	4	4	10	10	4	68
7	3009	3009-Cr-Batai-ML-DR-2-BEH-3	Chromium Chloride	rat	2	ppm	U	DR	12	w	NR	NR	MA	M	BEH	BEH	BHVR	WO		36	10	5	5	10	6	4	4	10	10	4	68
8																															
9	3729	3729-Cr-Ivank-ML-FD-1-PTH-6	Cr <sub>2</sub> O <sub>3</sub>	rat	3	g Cr <sub>2</sub> O <sub>3</sub> /kg BW	U	FD	90	d	100	d	MA	F	PTH	ORW	ORWT	KI	547		10	10	5	10	10	4	4	6	10	4	73
10	3061	3061-Cr-Meena-ML-GV-2-PTH-3	Chromic chloride	rat	1	mg Cr/kg BW/ day	M	GV	60	d	NR	NR	NR	M	PTH	HIS	HYPL	LI		10	10	8	10	10	10	4	4	1	10	4	71
11	3030	3030-Cr-Gentri-ML-FD-1-PTH-3	Chromium tripicolinate	sheep	2	mg C/kg diet	U	FD	84	d	NR	NR	JV	NR	PTH	OWT	SIMX	KI		14.2	10	10	5	5	6	4	4	10	10	4	68
12	3729	3729-Cr-Ivank-ML-FD-1-PTH-5	Cr <sub>2</sub> O <sub>3</sub>	rat	3	g Cr <sub>2</sub> O <sub>3</sub> /kg BW	U	FD	90	d	100	d	MA	F	PTH	ORW	ORWT	LI		547	10	10	5	10	10	4	4	10	10	4	77
13																															
14	3098	3098-Cr-Zahid-ML-FD-2-REP-3	Chromium sulphate	mouse	4	ppm compound	U	FD	35	d	NR	NR	JUV	M	REP	REP	TEWT	TE	5.8		10	10	5	10	7	10	4	1	10	4	71
15	3004	3004-Cr-Ande-ML-FD-1-REP-3	Chromium Chloride	rat	5	mg Cr/kg diet	U	FD	20	w	4	w	MA	NR	REP	REP	TEWT	TE	8.3		10	10	5	10	6	10	4	1	10	4	70
16	3009	3009-Cr-Batai-ML-DR-2-REP-6	Chromium Chloride	rat	2	ppm	U	DR	12	w	NR	NR	MA	M	REP	REP	RSUC	WO	36		10	5	5	10	6	10	4	8	10	4	72
17	3003	3003-Cr-Alham-ML-DR-1-REP-5	Chromium Chloride	mouse	2	ppm	U	DR	-n	d	-n	d	JUV	F	REP	REP	RSUC	WO	51		10	5	5	10	6	10	4	10	10	4	74
18	3025	3025-Cr-Elbet-ML-DR-1-REP-2	Chromium Chloride	mouse	4	ppm	U	DR	90	d	50	d	MA	M	REP	REP	PRFM	WO	91	228	10	5	5	10	6	10	10	10	10	4	80
19	3025	3025-Cr-Elbet-ML-DR-2-REP-3	Chromium Chloride	mouse	4	ppm	U	DR	90	d	50	d	MA	F	REP	REP	RSUC	WO	91	228	10	5	5	10	6	10	10	10	10	4	80
20	3025	3025-Cr-Elbet-ML-DR-1-REP-4	Chromium Chloride	mouse	4	ppm	U	DR	90	d	50	d	MA	M	REP	REP	RSUC	WO	228		10	5	5	10	6	10	4	6	10	4	70
21	3729	3729-Cr-Ivank-ML-FD-1-REP-7	Cr <sub>2</sub> O <sub>3</sub>	rat	3	g Cr <sub>2</sub> O <sub>3</sub> /kg BW	U	FD	90	d	100	d	MA	F	REP	REP	PROG	WO	547		10	10	5	10	10	4	1	10	4	74	
22	3098	3098-Cr-Zahid-ML-FD-2-REP-5	Chromium sulphate	mouse	4	ppm compound	U	FD	35	d	NR	NR	JUV	M	REP	REP	SPCV	TE		1.5	10	10	5	10	7	10	4	10	10	4	80
23	3009	3009-Cr-Batai-ML-DR-2-REP-4	Chromium Chloride	rat	2	ppm	U	DR	12	w	NR	NR	MA	M	REP	REP	RSEM	WO		36	10	5	5	10	6	10	4	10	10	4	74
24	3003	3003-Cr-Alham-ML-DR-1-REP-1	Chromium Chloride	mouse	2	ppm	U	DR	-n	d	-n	d	JUV	M	REP	REP	TEWT	TE		48.9	10	5	5	10	6	10	4	10	10	4	74
25	3003	3003-Cr-Alham-ML-DR-1-REP-6	Chromium Chloride	mouse	2	ppm	U	DR	-n	d	-n	d	JUV	F	REP	REP	RSEM	WO		50.6	10	5	5	10	6	10	4	10	10	4	74
26	3025	3025-Cr-Elbet-ML-DR-1-REP-3	Chromium Chloride	mouse	4	ppm	U	DR	90	d	50	d	MA	M	REP	REP	TEWT	TE		91.3	10	5	5	10	6	10	4	10	10	4	74
27	3025	3025-Cr-Elbet-ML-DR-2-REP-4	Chromium Chloride	mouse	4	ppm	U	DR	90	d	50	d	MA	F	REP	REP	OTHR	WO		228	10	5	5	10	6	10	4	10	10	4	74
28																															
29	3036	3036-Cr-Haste-ML-FD-1-GRO-1	Chromium picolinate	rat	6	mg C/kg diet	U	FD	12	w	21	d	JV	NR	GRO	GRO	BDWT	WO	0.12		10	10	5	10	7	8	4	10	10	4	78
30	3098	3098-Cr-Zahid-ML-FD-2-GRO-1	Chromium sulphate	mouse	4	pm chromium compound	U	FD	35	d	NR	NR	JUV	M	GRO	GRO	BDWT	WO	5.8		10	10	5	10	7	8	4	1	10	4	69
31	3004	3004-Cr-Ande-ML-FD-1-GRO-1	Chromium Chloride	rat	5	mg Cr/kg diet	U	FD	20	w	4	w	MA	NR	GRO	GRO	BDWT	WO	8.3		10	10	5	10	6	8	4	1	10	4	68
32	3025	3025-Cr-Elbet-ML-DR-2-GRO-1	Chromium Chloride	mouse	4	ppm	U	DR	90	d	50	d	MA	F	GRO	GRO	BDWT	WO	227		10	5	5	10	6	8	4	10	10	4	72
33	3729	3729-Cr-Ivank-ML-FD-1-GRO--3	Cr <sub>2</sub> O <sub>3</sub>	rat	3	g Cr <sub>2</sub> O <sub>3</sub> /kg BW	U	FD	90	d	100	d	MA	F	GRO	GRO	BDWT	WO	547		10	10	5	10	10	8	4	1	10	4	72
34	3009	3009-Cr-Batai-ML-DR-2-GRO-7	Chromium Chloride	rat	2	ppm	U	DR	12	w	NR	NR	MA	M	GRO	GRO	BDWT	WO		36	10	5	5	10	6	8	4	10	10	4	72
35	3003	3003-Cr-Alham-ML-DR-1-GRO-2	Chromium Chloride	mouse	2	ppm	U	DR	-n	d	-n	d	JUV	M	GRO	GRO	BDWT	WO		49	10	5	5	10	6	8	4	10	10	4	72
36	3003	3003-Cr-Alham-ML-DR-1-GRO-4	Chromium Chloride	mouse	2	ppm	U	DR	-n	d	-n	d	JUV	F	GRO	GRO	BDWT	WO		51	10	5	5	10	6	8	4	10	10	4	72
37	3025	3025-Cr-Elbet-ML-DR-1-GRO-1	Chromium Chloride	mouse	4	ppm	U	DR	90	d	50	d	MA	M	GRO	GRO	BDWT	WO		91	10	5	5	10	6	8	4	10	10	4	72
38																															
39	3061	3061-Cr-Meena-ML-GV-2-MOR-1	Chromic chloride	rat	1	mg Cr/kg BW/ day	M	GV	60	d	NR	NR	NR	M	MOR	MOR	MORT	WO	10		10	8	10	10	10	9	4	1	10	4	76
40	3729	3729-Cr-Ivank-ML-FD-1-MOR-1	Cr <sub>2</sub> O <sub>3</sub>	rat	3	g Cr <sub>2</sub> O <sub>3</sub> /kg BW	U	FD	90	d	100	d	MA	F	MOR	MOR	MORT	WO	547		10	10	5	10	10	9	4	1	10	4	73

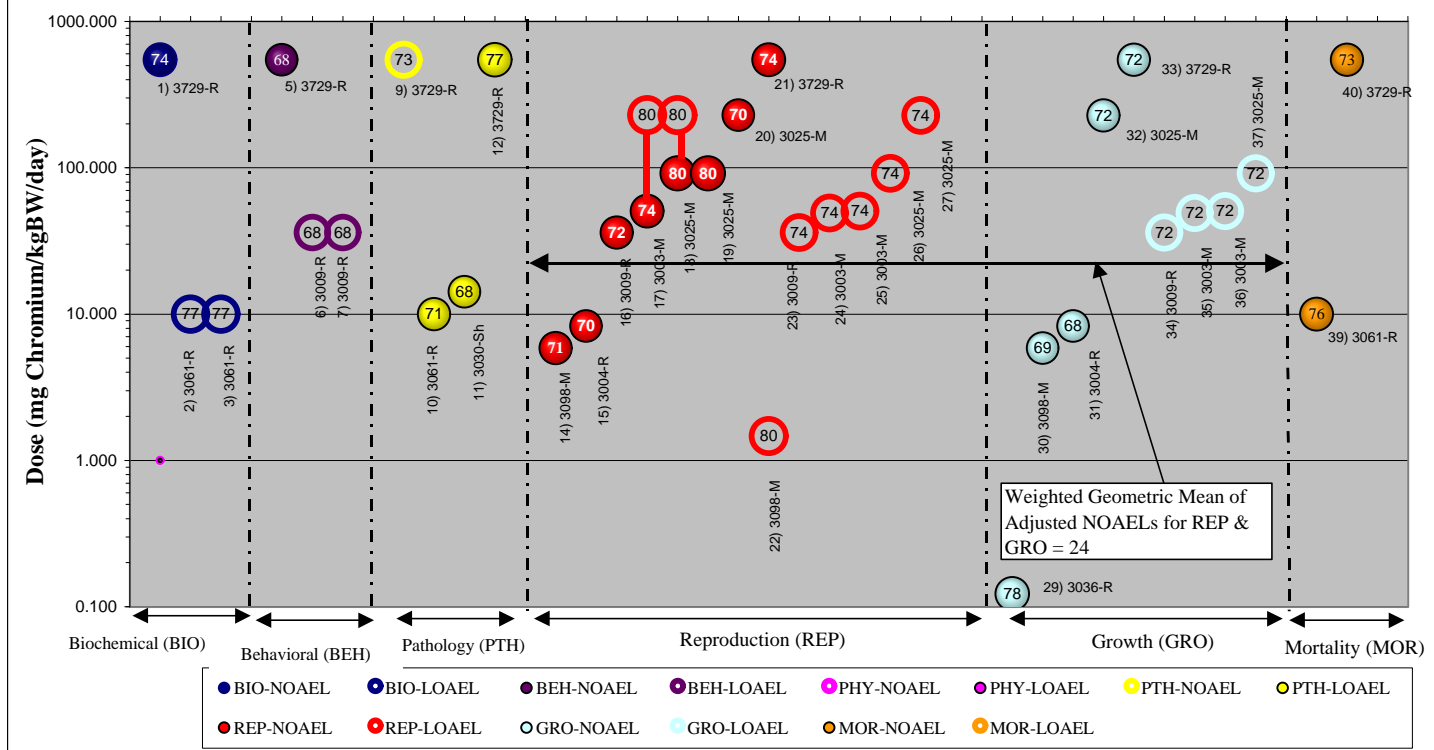
Table 3.2 Mammalian Toxicity Data for Hexavalent Chromium

TEST INFORMATION			EXPOSURE INFORMATION													EFFECTS INFORMATION					DATA EVALUATION SCORES											
Result #	Reference Number	Test ID	Chemical Form	Species	# of Conc/Doses	Reported Conc/Dose Units	Method of Chem Analyses	Route of Exposure	Exposure Duration	Duration Units	Age	Age Units	Lifestage	Sex	General Effect Group	Effect Type	Effect Measure	Response Site	NOAEL Dose (mg/kg/day)	LOAEL Dose (mg/kg/day)	Data Source	Dose Route	Test Substance	Chemical form	Dose Quantification	Endpoint	Dose Range	Statistical Power	Exposure Duration	Test Conditions	Total	
1	3074	3074-Cr-Rao-ML-FD-1-BIO-5	Chromate	mouse	2	ppm	M	FD	1	y	NR	NR	NR	BH	BIO	CHM	HMGL	BL	0.085		10	10	10	10	6	1	4	8	10	3	72	
2	3073	3073-Cr-Rao-ML-FD-1-BIO-3	Sodium chromate treated rice	rat	2	mg Cr in treated rice	M	FD	1	y	NR	NR	NR	BH	BIO	CHM	HMGL	BL	0.20		10	10	10	10	6	1	4	8	10	4	73	
3	3020	3010-Cr-Chowd-ML-GV-1-BIO-4	Sodium dichromate	mouse	4	mg Cr/kg BW/day	M	GV	90	d	NR	NR	NR	MA	M	BIO	ENZ	SCDH	TE	20	40	10	8	10	10	1	1	10	10	4	83	
4	3061	3061-Cr-Meena-ML-GV-1-BIO-2	Potassium dichromate	rat	1	mg Cr/kg BW/day	M	GV	60	d	NR	NR	NR	M	BIO	BIO	GLUC	BL		10	10	8	10	10	10	1	4	10	10	4	77	
5	3061	3061-Cr-Meena-ML-GV-1-BIO-4	Potassium dichromate	rat	1	mg Cr/kg BW/day	M	GV	60	d	NR	NR	NR	M	BIO	ENZ	OTHR	BL		10	10	8	10	10	10	1	4	10	10	4	77	
6	3020	3010-Cr-Chowd-ML-GV-1-BIO-5	Sodium dichromate	mouse	4	mg Cr/kg BW/day	M	GV	90	d	NR	NR	NR	MA	M	BIO	HRM	TSTR	BL	20	20	10	8	10	10	10	1	4	10	10	4	77
7																																
8	3074	3074-Cr-Rao-ML-FD-1-BEH-2	Chromate	mouse	2	ppm	M	FD	1	y	NR	NR	NR	BH	BEH	FDB	FCNS	WO	0.085		10	10	10	10	6	4	4	1	10	3	68	
9	3073	3073-Cr-Rao-ML-FD-1-BEH-1	Sodium chromate treated rice	rat	2	mg Cr in treated rice	M	FD	1	y	NR	NR	NR	BH	BEH	BEH	FCNS	WO	0.20		10	10	10	10	6	4	4	1	10	4	69	
10	3023	3023-Cr-Diazm-ML-DR-1-BEH-4	Sodium chromate	rat	3	g Cr (VI)	U	DR	28	d	NR	NR	NR	M	BEH	FDB	WCNS	WO	27	271.4	10	5	5	10	7	4	6	10	10	4	71	
11	3009	3009-Cr-Batai-ML-DR-1-BEH-3	Potassium dichromate	rat	2	ppm	U	DR	12	w	NR	NR	NR	MA	M	BEH	BEH	BHVR	WO		41.55	10	5	5	10	6	4	4	10	10	4	68
12																																
13	3023	3023-Cr-Diazm-ML-DR-1-PHY-5	Sodium chromate	rat	3	g Cr (VI)	U	DR	28	d	NR	NR	NR	M	PHY	PHY	EXCR	WO	27	271.4	10	5	5	10	7	4	6	10	10	4	71	
14																																
15	3074	3074-Cr-Rao-ML-FD-1-PTH-4	Chromate	mouse	2	ppm	M	FD	1	y	NR	NR	NR	BH	PTH	ORW	SMIX	LI	0.085		10	10	10	10	6	4	4	1	10	3	73	
16	3074	3074-Cr-Rao-ML-FD-1-PTH-3	Chromate	mouse	2	ppm	M	FD	1	y	NR	NR	NR	BH	PTH	PTH	GHIS	LI	0.085		10	10	10	10	6	4	4	1	10	3	68	
17	3073	3073-Cr-Rao-ML-FD-1-PTH-4	Sodium chromate treated rice	rat	2	mg Cr in treated rice	M	FD	1	y	NR	NR	NR	BH	PTH	ORW	ORWT	LI	0.20		10	10	10	10	6	4	4	1	10	4	78	
18	3020	3010-Cr-Chowd-ML-GV-1-PTH-6	Sodium dichromate	mouse	4	mg Cr/kg BW/day	M	GV	90	d	NR	NR	NR	MA	M	PTH	HIS	GHIS	TE	20	40	10	8	10	10	4	10	10	10	4	86	
19	3023	3023-Cr-Diazm-ML-DR-1-PTH-3	Sodium chromate	rat	3	g Cr (VI)	U	DR	28	d	NR	NR	NR	M	PTH	HIS	INCO	WO	27	271.4	10	5	5	10	7	4	6	10	10	4	71	
20	3061	3061-Cr-Meena-ML-GV-1-PTH-3	Potassium dichromate	rat	1	mg Cr/kg BW/day	M	GV	60	d	NR	NR	NR	M	PTH	HIS	HYPL	LI		10	10	8	10	10	10	4	4	1	10	4	71	
21																																
22	3073	3073-Cr-Rao-ML-FD-1-REP-5	Sodium chromate treated rice	rat	2	mg Cr in treated rice	M	FD	1	y	NR	NR	NR	M	REP	REP	OTHR	TE	0.20		10	10	10	10	6	10	4	10	10	4	84	
23	3098	3098-Cr-Zahid-ML-FD-1-REP-5	Potassium dichromate	mouse	4	ppm chromium compound	U	FD	35	d	NR	NR	JUV	M	REP	REP	SPCV	TE	2.1	4.2	10	10	5	10	7	10	10	10	10	4	86	
24	3098	3098-Cr-Zahid-ML-FD-1-REP-3	Potassium dichromate	mouse	4	ppm chromium compound	U	FD	35	d	NR	NR	JUV	M	REP	REP	TEWT	TE	8.4		10	10	5	10	7	10	4	1	10	4	71	
25	3020	3010-Cr-Chowd-ML-GV-1-REP-2	Sodium dichromate	mouse	4	mg Cr/kg BW/day	M	GV	90	d	NR	NR	NR	MA	M	REP	REP	TEWT	TE	20	40	10	8	10	10	10	10	10	10	4	92	
26	3068	3068-Cr-Murth-ML-DR-1-REP-3	Potassium dichromate	mouse	4	ppm Cr (VI)	U	DR	20	d	90	d	MA	F	REP	REP	OTHR	OV	35	70	10	5	5	10	6	10	10	10	6	4	76	
27	3045	3045-Cr-Junaid-ML-DR-1-REP-3	Potassium dichromate	mouse	4	ppm Cr (VI)	U	DR	7	d	50	d	MA	F	REP	REP	OTHR	WO	35	70	10	5	5	10	6	10	10	10	10	4	80	
28	3045	3045-Cr-Junaid-ML-DR-1-REP-4	Potassium dichromate	mouse	4	ppm Cr (VI)	U	DR	7	d	50	d	MA	F	REP	REP	TERA	WO	35	70	10	5	5	10	6	10	10	10	10	4	80	
29	3049	3049-Cr-Kanoj-ML-DR-1-REP-2	Potassium dichromate	rat	4	mg Cr/rat/day	U	DR	20	d	120	d	MA	F	REP	REP	NCLU	WO	37	70	10	5	5	10	10	10	10	10	10	4	84	
30	3003	3003-Cr-Alham-ML-DR-2-REP-1	Potassium dichromate	mouse	2	ppm	U	DR	-n	d	-n	d	JUV	M	REP	REP	TEWT	TE	39		10	5	5	10	6	10	4	10	10	4	74	
31	3009	3009-Cr-Batai-ML-DR-1-REP-6	Potassium dichromate	rat	2	ppm	U	DR	12	w	NR	NR	NR	MA	M	REP	REP	RSUC	WO	42		10	5	5	10	6	10	4	8	10	4	72
32	3003	3003-Cr-Alham-ML-DR-2-REP-4	Potassium dichromate	mouse	2	ppm	U	DR	-n	d	-n	d	JUV	M	REP	REP	OTHR	WO	42		10	5	5	10	6	10	4	10	10	4	74	
33	3026	3025-Cr-Elbet-ML-DR-3-REP-6	Potassium dichromate	mouse	5	ppm	U	DR	91	d	51	d	MA	M	REP	REP	RSUC	WO	53	105.4	11	5	5	10	6	10	10	10	10	4	81	
34	3046	3046-Cr-Junai-ML-DR-1-REP-3	Potassium dichromate	mouse	4	mg Cr/mouse/day	U	DR	20	d	4	m	MA	F	REP	REP	RSEM	WO	63	119	10	5	5	10	10	10	10	10	10	4	84	
35	3047	3047-Cr-Junai-ML-DR-1-REP-3	Potassium dichromate	mouse	4	mg Cr/mouse/day	U	DR	7	d	NR	NR	NR	MA	F	REP	REP	PROG	WO	67	125	10	5	5	10	10	10	10	10	6	4	80
36	3050	3050-Cr-Kanoj-ML-DR-1-REP-3	Potassium dichromate	rat	4	mg Cr/rat/day	U	DR	90	d	50	d	MA	F	REP	REP	OTHR	WO	70	127	10	5	5	10	10	10	10	10	10	4	84	
37	3049	3049-Cr-Kanoj-ML-DR-1-REP-7	Potassium dichromate	rat	4	mg Cr/rat/day	U	DR	20	d	120	d	MA	F	REP	REP	OTHR	WO	70	87.3	10	5	5	10	10	9	10	10	10	4	83	
38	3068	3068-Cr-Murth-ML-DR-1-REP-2	Potassium dichromate	mouse	4	ppm Cr (VI)	U	DR	20	d	90	d	MA	F	REP	REP	OTHR	OV	70	105.4	10	5	5	10	6	10	10	10	10	6	4	76
39	3049	3049-Cr-Kanoj-ML-DR-1-REP-4	Potassium dichromate	rat	4	mg Cr/rat/day	U	DR	20	d	120	d	MA	F	REP	REP	PRWT	WO	87		10	5	5	10	10	10	4	1	10	4	69	
40	3025	3025-Cr-Elbet-ML-DR-3-REP-3	Potassium dichromate	mouse	5	ppm	U	DR	90	d	50	d	MA	M	REP	REP	OTHR	WO	105	263.5	10	5	5	10	6	10	10	10	10	4	80	
41	3046	3046-Cr-Junai-ML-DR-1-REP-2	Potassium dichromate	mouse	4	mg Cr/mouse/day	U	DR	20	d	4	m	MA	F	REP	REP	NCLU	WO	119	174	10	5	5	10	10	10	10	10	10	4	84	
42	3047	3047-Cr-Junai-ML-DR-1-REP-6	Potassium dichromate	mouse	4	mg Cr/mouse/day	U	DR	7	d	NR	NR	NR	MA	F	REP	REP	TERA	WO	125	182	10	5	5	10	10	10	10	10	6	4	80
43	3050	3050-Cr-Kanoj-ML-DR-1-REP-4	Potassium dichromate	rat	4	mg Cr/rat/day	U	DR	90	d	50	d	MA	F	REP	REP	PROG	WO	170		10	5	5	10	10	10	4	1	10	4	69	
44	3047	3047-Cr-Junai-ML-DR-1-REP-2	Potassium dichromate	mouse	4	mg Cr/mouse/day	U	DR	7	d	NR	NR	NR	MA	F	REP	REP	NCLU	WO	182		10	5	5	10	10	10	4	10	6	4	74
45	3026	3025-Cr-Elbet-ML-DR-3-REP-7	Potassium dichromate	mouse	5																											

Table 3.3 Avian Toxicity Data for Trivalent Chromium

TEST INFORMATION			EXPOSURE INFORMATION										EFFECTS INFORMATION						DATA EVALUATION SCORES											
Result #	Reference Number	Test ID	Chemical Form	Species	# of Conc/ Doses	Method of Analyses	Route of Exposure	Exposure Duration	Duration Units	Age	Age Units	Lifestage	Sex	General Effect Group	Effect Type	Effect Measure	Response Site	NOAEL Dose (mg/kg/day)	LOAEL Dose (mg/kg/day)	Data Source	Dose Route	Test Substance	Chemical form	Dose Quantification	Endpoint	Dose Range	Statistical Power	Exposure Duration	Test Conditions	Total
1	3739	3739-Hase-AV-FD-BIO-12	Chrome alum	black duck	3	U	FD	1	y	NR	NR	MA	F	BIO	CHM	GLUC	BL	2.9		10	10	5	10	6	1	4	10	10	4	70
2	3739	3739-Hase-AV-FD-BIO-11	Chrome alum	black duck	3	U	FD	1	y	NR	NR	MA	F	BIO	CHM	HMGL	BL		2.9	10	10	5	10	6	1	4	10	10	4	70
3																														
4	3739	3739-Hase-AV-FD-REP-1	Chrome alum	black duck	3	U	FD	1	y	NR	NR	MA	F	REP	REP	RSUC	WO	0.57	2.9	10	10	5	10	6	10	8	10	10	4	83
5	3739	3739-Hase-AV-FD-REP-5	Chrome alum	black duck	3	U	FD	1	y	NR	NR	MA	F	REP	REP	PROG	WO	2.9		10	10	5	10	6	10	4	1	10	4	70
6	3739	3739-Hase-AV-FD-REP-6	Chrome alum	black duck	3	U	FD	1	y	NR	NR	MA	F	REP	REP	PRWT	WO	2.9		10	10	5	10	6	10	4	10	10	4	79
7	3038	3038-Cr-Heinz-AV-FD-REP-1	Chromium potassium sulfate	black duck	3	U	FD	5	m	2-3	y	NR	F	REP	REP	OTHR	WO	4.9		10	10	5	10	5	10	4	1	10	2	67
8																														
9	3739	3739-Hase-AV-FD-GRO-3	Chrome alum	black duck	3	U	FD	1	y	NR	NR	MA	F	GRO	GRO	BDWT	WO	2.9		10	10	5	10	6	8	4	10	10	4	77
10																														
11	3739	3739-Hase-AV-FD-MOR-4	Chrome alum	black duck	3	U	FD	1	y	NR	NR	MA	F	MOR	MOR	OTHR	WO	0.57	2.9	10	10	5	10	6	9	8	10	10	4	82
12	80	80-Cr-Vanvl-AV-FD-MOR-1	Chromium Chloride	chicken	2	U	FD	21	d	1	d	NR	NR	MOR	MOR	MORT	WO	32		10	10	5	10	5	9	4	1	10	2	66
13																														

Figure 3.1 Mammalian TRV Derivation for Trivalent Chromium



Result number → 1) 10 - C  
Reference Number → Test Species

**Test Species Key**  
C = chicken  
D = black duck

### Wildlife TRV Derivation Process

- 1) There are at least three results available for two test species within the GRO, REP and MOR effect groups. There is enough data to derive a TRV.
- 2) There are at least three NOAEL results available for calculation of a weighted geometric mean.
- 3) The weighted geometric mean of the adjusted NOAEL values for GRO and REP equals 24 mg Cr(III)/kg BW/day.
- 4) The weighted geometric mean of the adjusted NOAEL values cannot be compared to the lowest reported LOAEL or mortality as only NOAEL values are available.
- 5) The mammalian wildlife TRV for trivalent chromium is equal to the 24 mg Cr (III) /kg BW/day.

### **3.3 Mammalian Chromium TRVs**

#### ***Trivalent Chromium***

The NOAEL and LOAEL values for results with data evaluation scores above 65 are plotted on Figure 3.1 for trivalent chromium. The following steps were completed to identify a TRV.

- 1) There are at least three results available for growth (GRO), reproduction (REP) or mortality (MOR) endpoints for at least two test species. There is enough data to derive a TRV.
- 2) There are at least three NOAEL results available for GRO or REP to calculate a weighted geometric mean.
- 3) The NOAEL values are first adjusted based on their respective data evaluation score.

$$\text{Adjusted NOAEL} = \text{NOAEL} * (\text{Data Evaluation Score} / 100)$$

- 4) The weighted geometric mean of the adjusted NOAEL values is calculated as presented in Table 3.4 according to the following equation:

$$\log (\text{GeoMean}) = \{ \text{score}(1) * \log (\text{adj. NOAEL}(1)) + \dots + \text{score}(n) * \log (\text{adj. NOAEL}(n)) \} / \{ \text{sum of scores} \}$$

- 5) The weighted geometric mean NOAEL is lower than the lowest LOAEL for mortality.
- 6) The mammalian wildlife TRV for trivalent chromium is equal to the 24.5 mg Cr(III) /kg BW/day.

<b>Table 3.4</b> <b>Mammalian TRV Derivation for Trivalent Chromium</b> <b>Weighted Geometric Mean of Adjusted NOAELs</b>					
<b>Test ID</b>	<b>NOAELs</b>	<b>Scores</b>	<b>Adjusted NOAEL Value</b>	<b>Weight</b>	<b>Weight*Log Adj NOAEL</b>
3098-Cr-Zahid-ML-FD-2-REP-3	5.8	71	4.15	71	43.90
3004-Ande-ML-FD-1-REP-3	8.3	70	5.8	70	53.42
3009-Batai-ML-DR-2-REP-6	36	72	25.9	72	101.77
3003-Alham-ML-DR-1-REP-5	51	74	37.4	74	116.42
3025-Elbet-ML-DR-1-REP-2	91	80	73.1	80	149.10
3025-Elbet-ML-DR-2-REP-3	91	80	73.1	80	149.10
3025-Elbet-ML-DR-1-REP-4	228	70	159.8	70	154.26
3729-Ivank-ML-FD-1-REP-7	547	74	405.0	74	192.96
3036-Haste-ML-FD-1-GRO-1	0.12	78	0.1	78	-79.64
3098-Cr-Zahid-ML-FD-2-GRO-1	5.8	69	4.0	69	41.81
3004-Ande-ML-FD-1-GRO-1	8.3	68	5.6	68	51.04
3025-Elbet-ML-DR-2-GRO-1	227	72	163.8	72	159.43

Test ID	NOAELs	Scores	Adjusted NOAEL Value	Weight	Weight*Log Adj NOAEL
3729-Ivank-ML-FD-1-GRO--3	547	72	394.1	72	186.88
Sum				950	1320
(Sum of weight*log (adj NOAEL) / Sum of Weights					1.39
Weighted Geometric Mean					24.5

### Hexavalent Chromium

The NOAEL and LOAEL values for results with data evaluation scores above 65 are plotted on Figure 3.2 for hexavalent chromium. The following steps were completed to identify a TRV.

- 1) There are at least three results available for growth (GRO), reproduction (REP) or mortality (MOR) endpoints for at least two test species. There is enough data to derive a TRV.
- 2) There are at least three NOAEL results available for GRO or REP to calculate a weighted geometric mean.
- 3) The NOAEL values are first adjusted based on their respective data evaluation score.

$$\text{Adjusted NOAEL} = \text{NOAEL} * (\text{Data Evaluation Score} / 100)$$

- 4) The weighted geometric mean of the adjusted NOAEL values is calculated as presented in Table 3.5 according to the following equation:

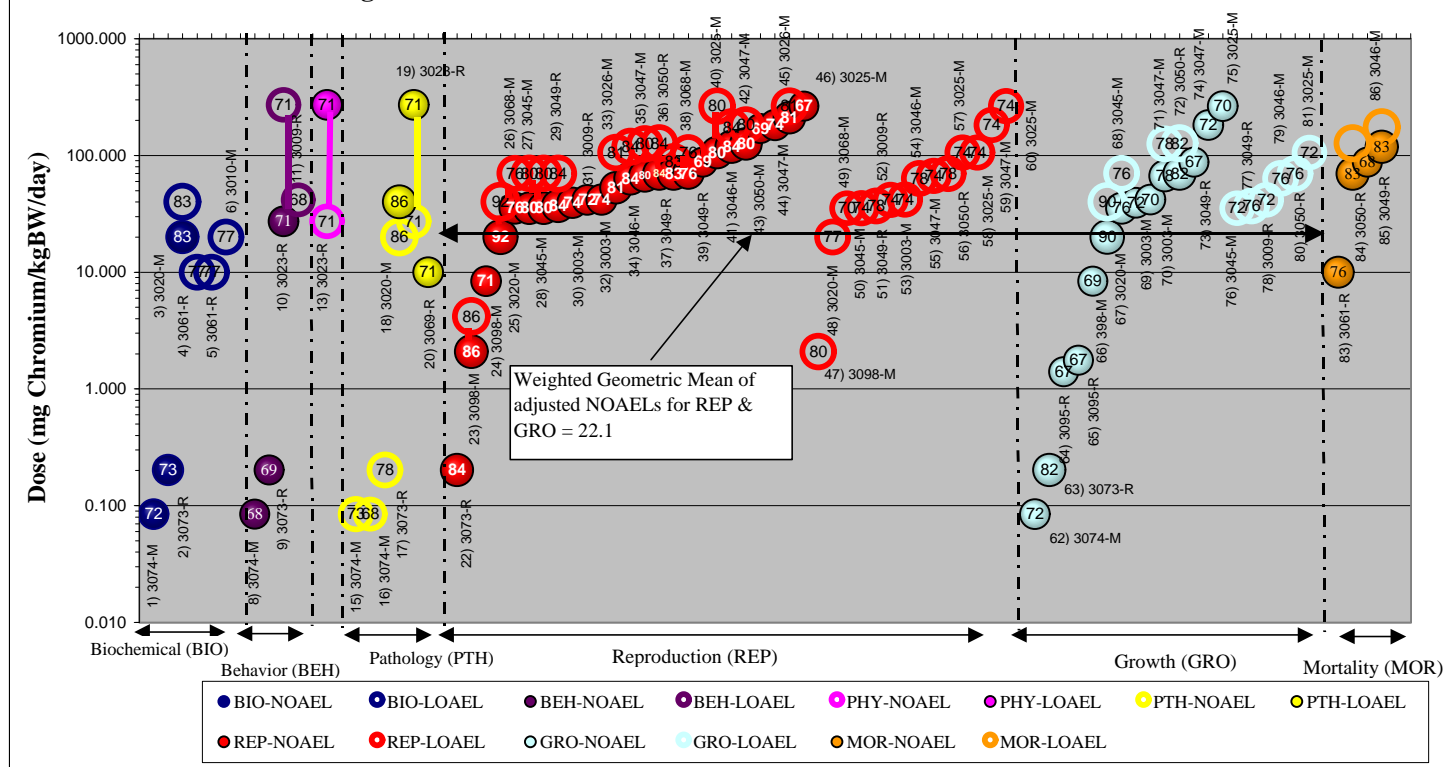
$$\log (\text{GeoMean}) = \{ \text{score}(1) * \log (\text{adj. NOAEL}(1)) + \dots + \text{score} (n) * \log (\text{adj. NOAEL}(n)) \} / \{\text{sum of scores}\}$$

- 5) The weighted geometric mean NOAEL is lower than the lowest LOAEL for mortality.
- 6) The mammalian wildlife TRV for hexavalent chromium is equal to the 22.1 mg Cr(VI) /kg BW/day.

Table 3.5 Mammalian TRV Derivation for Hexavalent Chromium Weighted Geometric Mean of NOAELs					
Test ID	NOAELs	Scores	Adjusted NOAEL Value	Weight	Weight*Log Adj NOAEL
3074-Cr-Rao-ML-FD-1-GRO-1	0.085	72	0.06	72	-87.47
3073-Cr-Rao-ML-FD-1-GRO-2	0.20	82	0.2	82	-64.18
3073-Cr-Rao-ML-FD-1-REP-5	0.20	84	0.2	84	-64.86
3095-Cr-Vysko-ML-DR-1-GRO-2	1.4	67	0.9	67	-1.86
3095-Cr-Vysko-ML-DR-2-GRO-2	1.8	67	1.2	67	4.80
3098-Cr-Zahid-ML-FD-1-REP-5	2.1	86	1.8	86	21.90

<b>Table 3.5</b> <b>Mammalian TRV Derivation for Hexavalent Chromium</b> <b>Weighted Geometric Mean of NOAELs</b>					
<b>Test ID</b>	<b>NOAELs</b>	<b>Scores</b>	<b>Adjusted NOAEL Value</b>	<b>Weight</b>	<b>Weight*Log Adj NOAEL</b>
3098-Cr-Zahid-ML-FD-1-GRO-1	8.4	69	5.8	69	52.51
3098-Cr-Zahid-ML-FD-1-REP-3	8.4	71	5.9	71	54.91
3010-Cr-Chowd-ML-GV-1-GRO-1	20	90	18.0	90	112.97
3010-Cr-Chowd-ML-GV-1-REP-2	20	92	18.4	92	116.36
3045-Cr-Junaid-ML-DR-1-GRO-1	35	76	26.7	76	108.43
3068-Cr-Murth-ML-DR-1-REP-3	35	76	26.7	76	108.43
3045-Cr-Junaid-ML-DR-1-REP-3	35	80	28.1	80	115.92
3003-Cr-Alham-ML-DR-2-GRO-2	39	72	28.2	72	104.46
3003-Cr-Alham-ML-DR-2-REP-1	39	74	29.0	74	108.24
3003-Cr-Alham-ML-DR-2-GRO-3	42	70	29.3	70	102.69
3009-Cr-Batai-ML-DR-1-REP-6	42	72	29.9	72	106.26
3049-Cr-Kanoj-ML-DR-1-REP-2	37	84	30.9	84	125.17
3003-Cr-Alham-ML-DR-2-REP-4	42	74	31.0	74	110.34
3025-Cr-Elbet-ML-DR-3-REP-6	53	81	42.7	81	132.05
3047-Cr-JunaI-ML-DR-1-GRO-1	67	78	52.0	78	133.85
3046-Cr-Junai-ML-DR-1-REP-3	63	84	53.2	84	144.98
3047-Cr-JunaI-ML-DR-1-REP-3	67	80	53.3	80	138.16
3068-Cr-Murth-ML-DR-1-REP-2	70	76	53.4	76	131.31
3050-Cr-Kanoj-ML-DR-1-GRO-1	70	82	57.1	82	144.04
3049-Cr-Kanoj-ML-DR-1-REP-7	70	84	57.9	83	148.04
3050-Cr-Kanoj-ML-DR-1-REP-3	70	84	58.5	84	148.43
3049-Cr-Kanoj-ML-DR-1-GRO-5	87	67	58.5	67	118.40
3049-Cr-Kanoj-ML-DR-1-REP-4	87	69	60.2	69	122.82
3025-Cr-Elbet-ML-DR-3-REP-3	105	80	84.3	80	154.07
3046-Cr-Junai-ML-DR-1-REP-2	119	84	99.7	84	167.88
3047-Cr-JunaI-ML-DR-1-REP-6	125	80	100.0	80	160.00
3050-Cr-Kanoj-ML-DR-1-REP-4	170	69	117.0	69	142.69
3047-Cr-JunaI-ML-DR-1-GRO-7	182	72	131.3	72	152.51
3047-Cr-JunaI-ML-DR-1-REP-2	182	74	134.9	74	157.63
3025-Cr-Elbet-ML-DR-3-REP-7	211	81	170.7	81	180.82
3025-Cr-Elbet-ML-DR-4-REP-4	263	67	176.5	67	150.54
3025-Cr-Elbet-ML-DR-4-GRO-2	263	70	184.4	70	158.61
Sum				2919	3920
(Sum of weight*log (adj NOAEL) / Sum of Weights					1.34
Weighted Geometric Mean					22

Figure 3.2 Mammalian TRV Derivation for Hexavalent Chromium



Result number → 1) 10 - C

Reference Number → Test Species

**Test Species Key**

R = rat  
M = mouse

#### Wildlife TRV Derivation Process

- 1) There are at least three results available for two test species within the GRO, REP and MOR effect groups. There is enough data to derive TRV.
- 2) There are at least three NOAEL results available for calculation of a weighted geometric mean.
- 3) The weighted geometric mean of the NOAEL values for GRO and REP equals 22.1 mg Cr(VI)/kg BW/day.
- 4) The weighted geometric mean NOAEL is lower than the lowest LOAEL for mortality.
- 5) The mammalian wildlife TRV for hexavalent chromium is equal to the 22.1 mg Cr(VI)/kg BW/day.



### 3.4 Avian Chromium TRVs

#### *Trivalent Chromium*

The NOAEL and LOAEL values for results with data evaluation scores above 65 are plotted on Figure 3.3 for trivalent chromium. The following steps were completed to identify a TRV.

- 1) There are at least three results available for growth (GRO), reproduction (REP) or mortality (MOR) endpoints for at least two test species. There is enough data to derive a TRV.
- 2) There are at least three NOAEL results available for GRO or REP to calculate a weighted geometric mean.
- 3) The NOAEL values are first adjusted based on their respective data evaluation score.

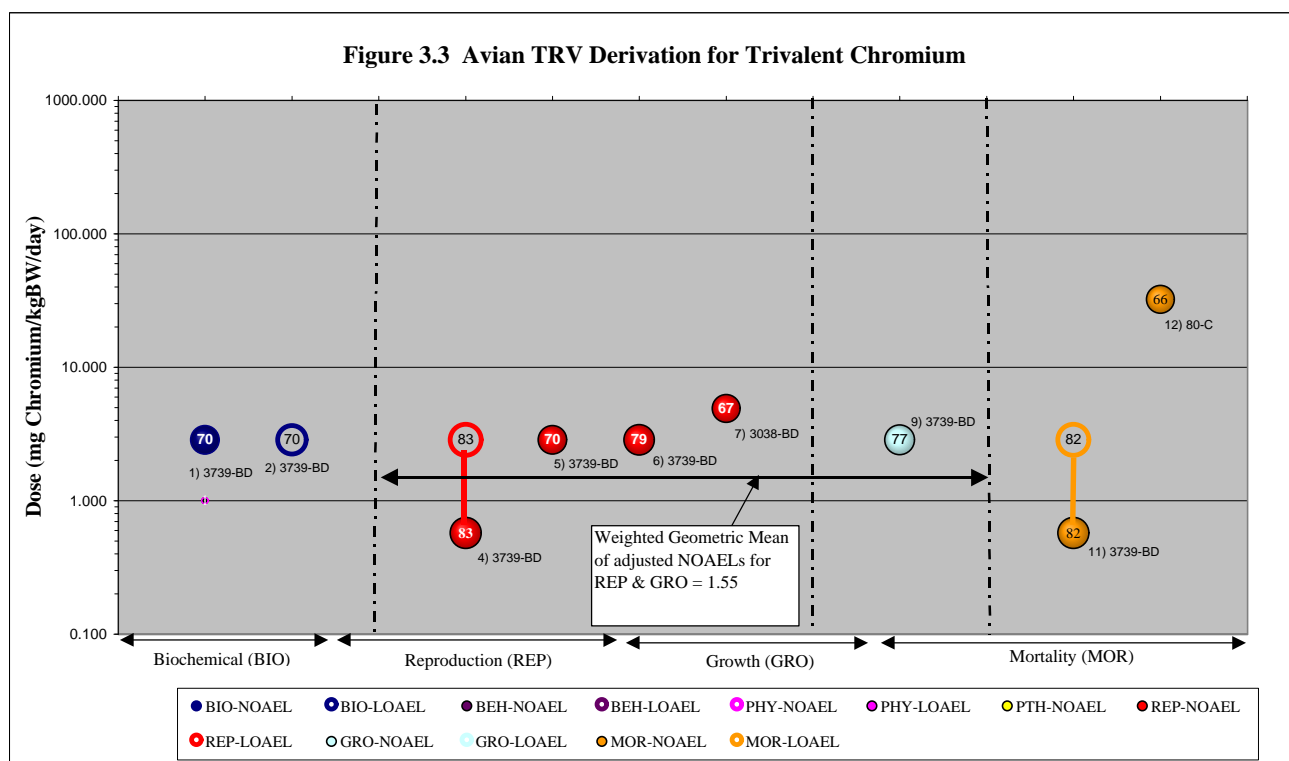
$$\text{Adjusted NOAEL} = \text{NOAEL} * (\text{Data Evaluation Score} / 100)$$

- 4) The weighted geometric mean of the adjusted NOAEL values is calculated as presented in Table 3.6 according to the following equation:

$$\log (\text{GeoMean}) = \{ \text{score}(1) * \log (\text{adj. NOAEL}(1)) + \dots + \text{score}(n) * \log (\text{adj. NOAEL}(n)) \} / \{ \text{sum of scores} \}$$

- 5) The weighted geometric mean NOAEL is lower than the lowest LOAEL for mortality.
- 6) The avian wildlife TRV for trivalent chromium is equal to the 1.55 mg Cr(III) /kg BW/day.

Table 3.6 Avian TRV Derivation for Trivalent Chromium Weighted Geometric Mean of Adjusted NOAELs					
Test ID	NOAELs	Scores	Adjusted NOAEL Value	Weight	Weight*Log Adj NOAEL
3739-Hase-AV-FD-REP-1	0.57	83	0.47	83	-26.88
3739-Hase-AV-FD-REP-5	2.86	70	2.0	70	21.08
3739-Hase-AV-FD-REP-6	2.86	79	2.3	79	27.94
3038-Cr-Heinz-AV-FD-REP-1	4.91	67	3.3	67	34.63
Sum				299	56.76
(Sum of weight*log (adj NOAEL) / Sum of Weights					0.1898
Weighted Geometric Mean					1.55



Result number → 1) 10 - C  
 Reference Number → 10 - C  
 Test Species → C

**Test Species Key**

C = chicken  
 BD = black duck

### Wildlife TRV Derivation Process

- 1) There are at least three results available for two test species within the GRO, REP and MOR effect groups. There is enough data to derive TRV.
- 2) There are at least three NOAEL results available for calculation of a weighted geometric mean.
- 3) The weighted geometric mean of the adjusted NOAEL values for GRO and REP equals 1.7 mg Cr (III)/kg BW/day.
- 4) The weighted geometric mean NOAEL value is less than the lowest reported LOAEL for mortality.
- 5) The avian wildlife TRV for trivalent chromium is equal to 1.7mg Cr(III)/kg BW/day.

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## **4.0 COBALT**

### **4.1 Literature Search, Retrieval and Review**

The electronic literature search for cobalt toxicity data was completed according to the procedures provided in Exhibit 4-1. The search results are reported as four separate lists. The first list contains studies identified during the electronic search that were rejected for use based on a review of the abstract and title. This list is included as Attachment A to this appendix. The second list reports the literature for which useful toxicological data was identified and extracted (literature used). The third list reports the literature that was retrieved, reviewed and then rejected (literature rejected). The fourth list contains literature identified in the search that either could not be retrieved for review or has not been received for review (literature pending). These references are listed as Section 4.5.

Each of the citations in these lists are identified with a unique record number assigned as part of the data extraction process as described in Appendix 4-3 (SOP #2). Citations on the “literature not coded” list are labeled with respective literature rejection criteria also described in Appendix 4-3 (SOP #2).

### **4.2 Data Review and Evaluation**

The electronic and manual literature search process (Exhibit 4-1) for cobalt identified 115 total studies for retrieval and review. Of these, 30 studies contained data extracted and used to derive the Eco-SSL, 85 studies were rejected for use and two studies could not be located for review.

#### ***Mammalian Data***

Data was extracted from twenty-three studies for derivation of the mammalian TRV for cobalt. The data reviewed and extracted from these studies is summarized in Table 4.1.

#### ***Avian Data***

Data was extracted from the seven studies for derivation of the avian cobalt TRV. The data reviewed and extracted from these studies is summarized in Table 4.2.

### **4.3 Mammalian Cobalt TRV**

The NOAEL and LOAEL values for results with data evaluation scores above 65 are plotted on Figure 4.1 for cobalt. The following steps were completed to identify a TRV.

- 1) There are at least three results available for growth (GRO), reproduction (REP) or mortality (MOR) endpoints for at least two test species. There is enough data to derive a TRV.

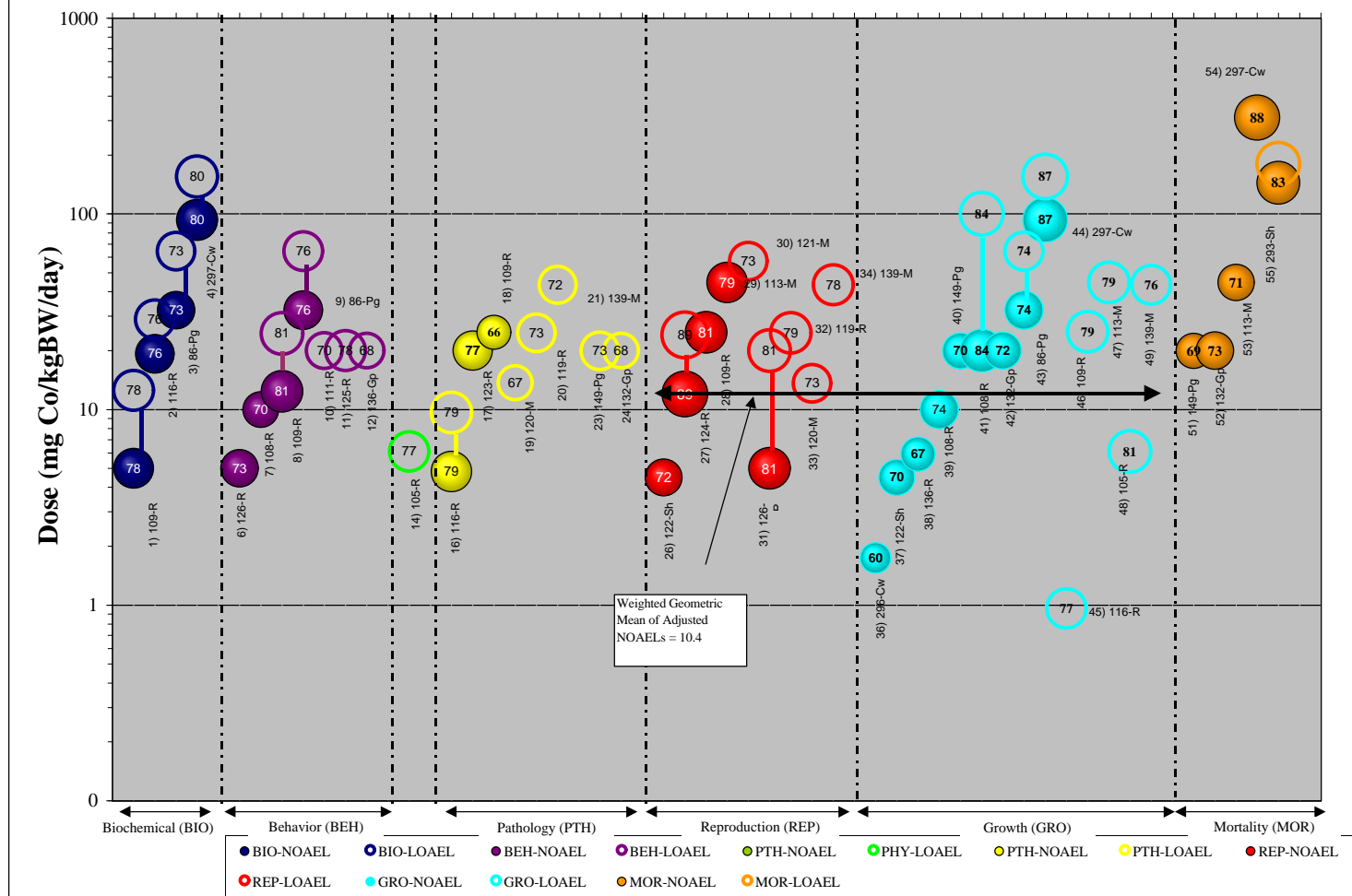
**Table 4.1**  
**Mammalian Toxicity Data for Cobalt**

TEST INFORMATION			EXPOSURE INFORMATION										EFFECT INFORMATION				DATA EVALUATION SCORE													
Result #	TEST ID	Chemical Form	Common name	# of Conc/ Doses	Conc/Dose Units	Method of Analyses	Route of Exposure	Exposure Duration	Duration Units	Age	Age Units	Lifespan	Sex	General Effect Group	Effect Type	Effect Measure	NOAEL Dose (mg/kg/day)	LOAEL Dose (mg/kg/day)	Data Source	Dose Route	Test Concentrations	Chemical form	Dose Quantification	Endpoint	Dose Range	Statistical Power	Exposure Duration	Test Conditions	Total	
1	109-Co-Pater-ML-GV-1-BIO-1	Cobalt (II)chloride hexahydrate	rat	4	mg/kg BW/day	U	GV	gestation		NR	NR	MA	F	BIO	CHM	CREA	5	13		10	8	5	10	10	1	10	10	4	7	
2	116-Co-Chett-ML-FD-1-BIO-4	cobaltous chloride	rat	6	ppm	U	FD	4	wk	NR	NR	NR	BH	BIO	CHM	HMGL	19	29		10	10	5	10	6	1	10	10	4	7	
3	86-Co-Huck-ML-FD-1-BIO-1	Cobalt chloride hexahydrate	pig	4	mg Co/kg	U	FD	16	wk	NR	NR	NR	NR	BIO	CHM	HMGL	32	64		10	10	5	10	7	1	10	10	6	4	
4	297-Co-Keen-ML-DR-1-BIO-3	Cobaltous sulfate	cow	4	mg/d/100lb BW	U	FD	13	wk	48	w	MA	F	BIO	CHM	HMGL	93	155		10	10	5	10	10	1	10	10	4	8	
5																														
6	126-Co-Natio-ML-FD-1-BEH-1	cobalt chloride	rat	3	mg/kg BW/day	U	FD	69	d	80	d	MA	F	BEH	BEH	ACTP	5			10	10	5	10	10	4	4	10	6	7	
7	108-Co-Pehrs-ML-FD-1-BEH-1	cobalt sulfate	rat	2	mg/kg BW/day	U	FD	8	wk	NR	NR	NR	M	BEH	FDB	FCNS	10			10	10	5	10	10	4	4	10	3	4	
8	109-Co-Pater-ML-GV-1-BEH-2	Cobalt chloride hexahydrate	rat	4	mg/kg BW/day	U	GV	gestation		NR	NR	MA	F	BEH	FDB	FCNS	12	24		10	8	5	10	10	4	4	10	10	4	
9	86-Co-Huck-ML-FD-1-BEH-2	Cobalt chloride hexahydrate	pig	4	mg Co/kg	U	FD	16	wk	NR	NR	NR	NR	BEH	FDB	FCNS	32	64		10	10	5	10	7	4	10	10	6	7	
10	111-Co-Bourg-ML-DR-1-BEH-1	cobalt chloride	rat	2	mg Co/kg BW/day	M	DR	57	d	80	d	NR	M	BEH	BEH	ACTP	20			10	10	5	10	10	4	4	10	3	4	
11	125-Co-Wellm-ML-FD-1-BEH-1	cobalt chloride	rat	4	mg Co/kg BW/day	U	FD	14	d	60	d	MA	M	BEH	FDB	FCNS	20			10	10	10	10	10	4	4	10	6	4	
12	132-Co-Mohiu-ML-OR-1-BEH-1	cobalt sulfate	guinea pig	2	mg/kg BW/day	U	OR	5	wk	NR	NR	NR	M	BEH	FDB	FCNS	20			10	8	5	10	10	4	4	10	3	6	
13																														
14	105-Co-Haga-ML-FD-1-PHY-1	cobalt sulfate	rat	2	mg/kg BW/day	U	FD	24	wk	NR	NR	NR	M	PHY	PHY	HTRT		6.1		10	10	5	10	10	4	4	10	10	4	
15																														
16	116-Co-Chett-ML-FD-1-PTH-2	cobaltous chloride	rat	6	ppm	U	FD	4	wk	NR	NR	NR	BH	PTH	ORW	SMIX	4.8	9.6		10	10	5	10	6	4	10	10	4	7	
17	123-Co-Cori-ML-FD-1-PTH-1	cobalt chloride hexahydrate	rat	2	mg Co/kg BW	U	FD	98	d	100	d	MA	M	PTH	HIS	GHIS	20			10	10	5	10	10	4	4	10	10	4	
18	109-Co-Pater-ML-GV-1-PTH-3	Cobalt chloride hexahydrate	rat	4	mg/kg BW/day	U	GV	gestation		NR	NR	MA	F	PTH	PTH	ORWT	25			10	8	5	10	10	4	4	1	10	4	
19	120-Co-Ander-ML-DR-1-PTH-1	cobalt chloride hexahydrate	mouse	2	mg/L	U	DR	13	wk	12	w	MA	M	PTH	HIS	GHIS		14		10	5	5	10	5	4	4	10	10	4	
20	119-Co-Molle-ML-FD-1-PTH-1	NR	rat	2	ppm	U	FD	100	d	98	d	MA	M	PTH	HIS	GHIS	25			10	10	5	10	6	4	4	10	10	4	
21	139-Co-Ander-ML-DR-1-PTH-1	cobalt chloride	mouse	2	mg Co/kg BW/day	U	DR	13	wk	12	w	MA	M	PTH	HIS	GHIS	43			10	5	5	10	10	4	4	10	10	4	
22	122-Co-Cori-ML-OR-1-PTH-2	Cobalt chloride hexahydrate	sheep	3	mg Co/kg BW	U	OR	109	d	1	d	MA	M	PTH	HIS	GLNS				10	8	5	10	10	4	4	1	10	4	
23	149-Co-Vanvl-ML-FD-1-PTH-2	cobalt chloride	pig	2	mg/kg	U	FD	10	wk	NR	NR	JV	M	PTH	HIS	GLSN	20			10	10	5	10	6	4	4	10	10	4	
24	132-Co-Mohiu-ML-OR-1-PTH-2	cobalt sulfate	guinea pig	2	mg/kg BW/day	U	OR	5	wk	NR	NR	NR	M	PTH	HIS	GLSN	20			10	8	5	10	10	4	4	10	3	6	
25																														
26	122-Co-Cori-ML-OR-1-REP-3	Cobalt chloride hexahydrate	sheep	3	mg Co/kg BW	U	OR	109	d	1	d	MA	M	REP	REP	TEWT	4.5			10	8	5	10	10	10	4	1	10	4	
27	124-Co-Domin-ML-OR-1-REP-1	cobalt chloride	rat	4	mg/kg BW/day	U	OR					MA	F	REP	REP	PRWT	12	24		10	10	5	10	10	10	10	10	10	4	
28	109-Co-Pater-ML-GV-1-REP-4	Cobalt chloride hexahydrate	rat	4	mg/kg BW/day	U	GV	gestation		NR	NR	MA	F	REP	REP	PRWT	25			10	8	5	10	10	10	4	4	10	10	4
29	113-Co-Seide-ML-OR-1-REP-1	cobalt chloride	mouse	2	mg/kg BW/day	U	OR	gestation		NR	NR	MA	F	REP	REP	PROG	45			10	8	5	10	10	10	4	10	8	4	
30	121-Co-Pedig-ML-DR-1-REP-1	Cobalt chloride hexahydrate	mouse	22	mg Co/kg	U	DR	gestation		8-10	w	MA	BH	REP	REP	RPRD	57			10	5	5	10	5	10	4	10	10	4	
31	126-Co-Natio-ML-FD-1-BEH-1	cobalt chloride	rat	3	mg/kg BW/day	U	FD	69	d	80	d	MA	F	REP	REP	TEWT	5	20		10	10	5	10	10	10	6	10	6	4	
32	119-Co-Molle-ML-FD-1-REP-2	NR	rat	2	ppm	U	FD	100	d	98	d	MA	M	REP	REP	TEWT	25			10	10	5	10	6	10	4	10	10	4	
33	120-Co-Ander-ML-DR-1-REP-2	Cobalt chloride hexahydrate	mouse	2	mg/L	U	DR	13	wk	12	w	MA	M	REP	REP	TEWT	14			10	5	5	10	5	10	4	10	10	4	
34	139-Co-Ander-ML-DR-1-REP-2	cobalt chloride	mouse	2	mg Co/kg BW/day	U	DR	13	wk	12	w	MA	M	REP	REP	TEWT	43			10	5	5	10	10	10	4	10	10	4	
35																														
36	296-Co-Ely-ML-FD-1-GRO-1	cobalt sulfate	cow	2	ppm	U	FD	4	d	120	d	MA	NR	GRO	GRO	BDWT	1.7			10	10	5	10	7	8	4	1	3	2	
37	122-Co-Cori-ML-OR-1-GRO-4	Cobalt chloride hexahydrate	sheep	3	mg Co/kg BW	U	OR	109	d	1	d	MA	M	GRO	GRO	BDWT	4.5			10	8	5	10	10	8	4	1	10	4	
38	136-Co-Gersh-ML-FD-1-GRO-2	Cobalt chloride hexahydrate	rat	2	ppm	U	FD	80	d	44	d	JV	M	GRO	GRO	BDWT	5.9			10	10	5	10	5	8	4	1	10	4	
39	108-Co-Pehrs-ML-FD-1-GRO-2	cobalt sulfate	rat	2	mg/kg BW/day	U	FD	8	wk	NR	NR	NR	M	GRO	GRO	BDWT	10			10	10	5	10	10	8	4	10	3	4	
40	149-Co-Vanvl-ML-FD-1-GRO-3	cobalt chloride	pig	2	mg/kg	U	FD	10	wk	NR	NR	JV	M	GRO	GRO	BDWT	20			10	10	5	10	6	8	4	3	10	4	
41	125-Co-Wellm-ML-FD-1-BEH-1	cobalt chloride	rat	4	mg Co/kg BW/day	U	FD	14	d	60	d	MA	M	GRO	GRO	BDWT	20	100		10	10	10	10	10	8	6	10	6	4	
42	132-Co-Mohiu-ML-OR-1-GRO-3	cobalt sulfate	guinea pig	2	mg/kg BW/day	U	OR	5	wk	NR	NR	MA	M	GRO	GRO	BDWT	20			10	8	5	10	10	8	4	10	3	4	
43	86-Co-Huck-ML-FD-1-GRO-3	Cobalt chloride hexahydrate	pig	4	mg Co/kg	U	FD	16	wk	NR	NR	NR	NR	GRO	GRO	BDWT	32	64		10	10	5	10	7	8	4	10	6	4	
44	297-Co-Keen-ML-DR-1-GRO	Cobaltous sulfate	cow	4	mg/d/100lb BW	U	FD	13	wk	48	w	MA	F	GRO	GRO	BDWT	93	155		10	10	5	10	10	8	10	10	10	4	
45	116-Co-Chett-ML-FD-1-GRO-1	cobaltous chloride	rat	6	ppm	U	FD	4	wk	NR	NR	NR	BH	GRO	GRO	BDWT		0.96		10	10	5	10	6	8	4	10	10	4	
46	109-Co-Pater-ML-GV-1-GRO-5	Cobalt chloride hexahydrate	rat	4	mg/kg BW/day	U	GV	gestation		NR	NR	MA	F	GRO	GRO	BDWT	25			10	8	5	10	10	8	4	10	10	4	
47	113-Co-Seide-ML-OR-1-GRO-2	cobalt chloride	mouse	2	mg/kg BW/day	U	OR	gestation		NR	NR	MA	F	GRO	GRO	BDWT	45			10	8	5	10	10	8	4	10	10	4	
48	105-Co-Haga-ML-FD-1-GRO-2	cobalt sulfate	rat	2	mg/kg BW/day	U	FD	24	wk	NR	NR	NR	M	GRO	GRO	BDWT	6.1			10	10	5	10	10	8	4	10	10	4	
49	139-Co-Ander-ML-DR-1-GRO-3	cobalt chloride	mouse	2	mg Co/kg BW/day	U	DR	13	wk	12	w	MA	M	GRO	GRO	BDWT	43			10	5	5	10	10	8	4	10	10	4	
50																														
51	149-Co-Vanvl-ML-FD-1-MOR-4	cobalt chloride	pig	2	mg/kg	U	FD	10	wk	NR	NR	JV	M	MOR	MOR	MORT	20			10	10	5	10	6	9	4	1	10	4	
52	132-Co-Mohiu-ML-OR-1-MOR-4	cobalt sulfate	guinea pig	2	mg/kg BW/day	U	OR	5	wk	NR	NR	MA	M	MOR	MOR	SURV	20			10	8	5	10	10	9	4	10	3	4	
53	113-Co-Seide-ML-OR-1-MOR-3	cobalt chloride	mouse	2	mg/kg BW/day	U	OR	gestation		NR	NR	MA	F	MOR	MOR	SURV	45			10	8	5	10	10	9	4	1	10	4	
54	297-Co-Keen-ML-DR-1-MOR	Cobaltous sulfate	cow	4	mg/d/100lb BW	U	FD	13	wk	48	w	MA	F	MOR	MOR	MORT	310			10	10	5	10	10	9	10	10	10	4	
55	293-Co-Becke-ML-FD-1-MOR-1	Cobalt chloride hexahydrate	sheep	9	mg/centweight/day	U	FD	5	wk	NR	NR	NR	NR	MOR	MOR	MORT	144	180		10	10	5	10	5	9	10	10	10	4	

Table 4.2 Avian Toxicity Data for Cobalt

TEST INFORMATION				EXPOSURE INFORMATION										EFFECT INFORMATION					DATA EVALUATION SCORE											
Result #	Test ID	Chemical Form	Species	# of Conc/ Doses	Conc/Dose Units	Method of Analyses	Exposure Route	Exposure Duration	Age	Age Units	Lifestage	Sex	General Effect Group	Effect Type	Effect Measure	Response Site	NOAEL Dose (mg/kg/day)	LOAEL Dose (mg/kg/day)	Data Source	Dose Route	Test Concentrations	Chemical form	Dose Quantification	Endpoint	Dose Range	Statistical Power	Exposure Duration	Test Conditions	Total	
1	84-Co-Paulo-AV-FD-1-BIO-1	Cobalt chloride hexahydrate	Duck	2	%diet	U	FD	3	w	JV	2	d	NR	BIO	CHEM	TFAA	HE		53.5	10	10	5	10	5	1	4	10	10	4	69
2	91-Co-Paulo-AV-FD-1-BIO-1	Cobalt chloride hexahydrate	Duck	3	%diet	U	FD	20	d	JV	2	d	NR	BIO	CHM	ALB	BL		18.5	10	10	1	10	6	1	4	10	10	4	66
3	100-Co-Diaz-AV-FD-1-BIO-1	Cobalt chloride hexahydrate	Chicken	4	ppm	U	FD	42	d	JV	1	d	BH	BIO	CHM	RBCE	BL	2.7	13	10	10	5	10	5	1	8	10	10	4	73
4																														
5	90-Co-Diaz-AV-FD-1-BEH-2	Cobalt chloride hexahydrate	Chicken	4	mg/kg Co	M	FD	14	d	JV	1	d	M	BEH	FDB	FCNS	WO	20	44	10	10	10	10	7	4	10	10	10	4	85
6	100-Co-Diaz-AV-FD-1-BEH-2	Cobalt chloride hexahydrate	Chicken	4	ppm	U	FD	42	d	JV	1	d	BH	BEH	FDB	FCNS	WO		24	10	10	5	10	7	4	4	10	10	4	74
7																														
8	90-Co-Diaz-AV-FD-1-PTH-3	Cobalt chloride hexahydrate	Chicken	4	mg/kg Co	M	FD	14	d	JV	1	d	M	PTH	HIS	GLSN	WO	20	44	10	10	10	10	7	9	4	10	10	4	85
9	80-Co-Vanvl-AV-1-FD-PTH-1	Cobalt chloride hexahydrate	Duck	3	mg/kg as Co	U	FD	15	d	JV	1	d	M	PTH	MUSC	GLSN	WO		21	10	10	5	10	5	9	4	10	10	4	77
10	100-Co-Diaz-AV-FD-1-PTH-4	Cobalt chloride hexahydrate	Chicken	4	ppm	U	FD	42	d	JV	1	d	BH	PTH	MPH	ORWT	HE		24	10	10	5	10	7	4	4	10	10	4	74
11																														
12	90-Co-Diaz-AV-FD-1-GRO-1	Cobalt chloride hexahydrate	Chicken	4	mg/kg Co	M	FD	14	d	JV	1	d	M	GRO	GRO	BDWT	WO		21	10	10	10	10	7	8	4	10	10	4	83
13	92-Co-Hill-AV-FD-1-GRO-1	Cobalt chloride hexahydrate	Chicken	6	mg/kg diet	U	FD	2	w	JV	1	d	NR	GRO	GRO	BDWT	WO	1.3	2.6	10	10	6	10	5	8	10	10	10	4	83
14	91-Co-Paulo-AV-FD-1-GRO-1	Cobalt chloride hexahydrate	Duck	3	%diet	U	FD	20	d	JV	2	d	NR	GRO	GRO	BDWT	WO		18.5	10	10	1	10	6	8	4	10	10	4	73
15	81-Co-South-AV-FD-1-GRO-1	Cobalt chloride hexahydrate	Chicken	3	ug/g	U	FD	14	d	JV	8	d	M	GRO	GRO	BDWT	WO		8.60	10	10	5	10	6	8	4	10	10	4	77
16	100-Co-Diaz-AV-FD-1-GRO-3	Cobalt chloride hexahydrate	Chicken	4	ppm	U	FD	42	d	JV	1	d	BH	GRO	GRO	BDWT	WO		24	10	10	5	10	7	8	4	10	10	4	78
17																														
18	90-Co-Diaz-AV-FD-1-MOR-4	Cobalt chloride hexahydrate	Chicken	4	mg/kg Co	M	FD	14	d	JV	1	d	M	MORT	MORT	MORT	WO		21	10	10	10	10	7	9	4	10	10	4	84
19	92-Co-Hill-AV-FD-1-MOR-2	Cobalt chloride hexahydrate	Chicken	6	mg/kg diet	U	FD	2	w	JV	1	d	NR	MORT	MORT	MORT	WO	2.6	5.2	10	10	6	10	5	9	10	10	10	4	84
20	80-Co-Vanvl-AV-FD-1-MOR-2	Cobalt chloride hexahydrate	Duck	3	mg/kg as Co	U	FD	15	d	JV	1	d	M	MORT	MORT	MORT	WO	21.4		10	10	5	10	5	9	4	10	10	4	77
21	80-Co-Vanvl-AV-FD-2-MOR-1	Cobalt chloride hexahydrate	Duck	3	mg/kg as Co	U	FD	28	d	JV	1	d	M	MORT	MORT	MORT	WO		53.5	10	10	5	10	5	9	4	1	10	4	68
22	100-Co-Diaz-AV-FD-1-MOR-5	Cobalt chloride hexahydrate	Chicken	4	ppm	U	FD	42	d	JV	1	d	BH	MORT	MORT	MORT	WO	24		10	10	5	10	7	9	4	1	10	4	70
23																														

**Figure 4.1 Mammalian TRV Derivation for Cobalt**



### Wildlife TRV Derivation Process

- 1) There are at least three results available for two test species within the GRO, REP and MOR effect groups. There is enough data to derive TRV.
- 2) There are at least three NOAEL results available for calculation of a weighted geometric mean.
- 3) The weighted geometric mean of the adjusted NOAEL values for GRO and REP equals 10.4 mg Co/kg BW/day.
- 4) The weighted geometric mean NOAEL value is less than the lowest reported LOAEL for mortality.
- 5) The mammalian wildlife TRV for cobalt is equal to 10.4mg Co/kg BW/day.

- 2) There are at least three NOAEL results available for GRO or REP to calculate a weighted geometric mean.
- 3) The NOAEL values are first adjusted based on their respective data evaluation score.

$$\text{Adjusted NOAEL} = \text{NOAEL} * (\text{Data Evaluation Score} / 100)$$

- 4) The weighted geometric mean of the adjusted NOAEL values is calculated as presented in Table 4.3 according to the following equation:

$$\log (\text{GeoMean}) = \{ \text{score}(1) * \log (\text{adj. NOAEL}(1)) + \dots + \text{score}(n) * \log (\text{adj. NOAEL}(n)) \} / \{\text{sum of scores}\}$$

- 5) The weighted geometric mean NOAEL is lower than the lowest LOAEL for mortality.
- 6) The mammalian wildlife TRV for cobalt is equal to the 10.4 mg Co /kg BW/day.

<b>Table 4.3</b>					
<b>Mammalian TRV Derivation for Cobalt Weighted Geometric Mean of Adjusted NOAELs</b>					
<b>Test ID</b>	<b>NOAELs</b>	<b>Scores</b>	<b>Adjusted NOAEL Value</b>	<b>Weight</b>	<b>Weight*Log Adj NOAEL</b>
122-Co-Corri-ML-OR-1-REP-3	4.5	72	3.24	72	36.76
124-Co-Domin-ML-OR-1-REP-1	12	89	10.7	89	91.54
109-Co-Pater-ML-GV-1-REP-4	25	81	20.1	81	105.50
113-Co-Seide-ML-OR-1-REP-1	45	79	35.2	79	122.20
126-Co-Natio-ML-FD-1-BEH-1	5	81	4.1	81	49.20
296-Co-Ely-ML-FD-1-GRO-1	1.7	60	1.0	60	1.11
122-Co-Corri-ML-OR-1-GRO-4	4.5	70	3.2	70	34.88
136-Co-Gersh-ML-FD-1-GRO-2	5.9	67	4.0	67	40.02
108-Co-Pehrs-ML-FD-1-GRO-2	10	74	7.4	74	64.32
149-Co-Vanvl-ML-FD-1-GRO-3	19.9	70	14.0	70	80.15
125-Co-Wellm-ML-FD-1-BEH-1	20	84	16.8	84	102.93
132-Co-Mohiu-ML-OR-1-GRO-3	20	72	14.4	72	83.40
86-Co-Huck-ML-FD-1-GRO-3	32.1	74	23.8	74	101.85
297-Co-Keen-ML-DR-1-GRO	93.0	87	80.9	87	165.98
Sum				1060	1080
(Sum of weight*log (adj NOAEL) / Sum of Weights					1.0187
Weighted Geometric Mean					10.4

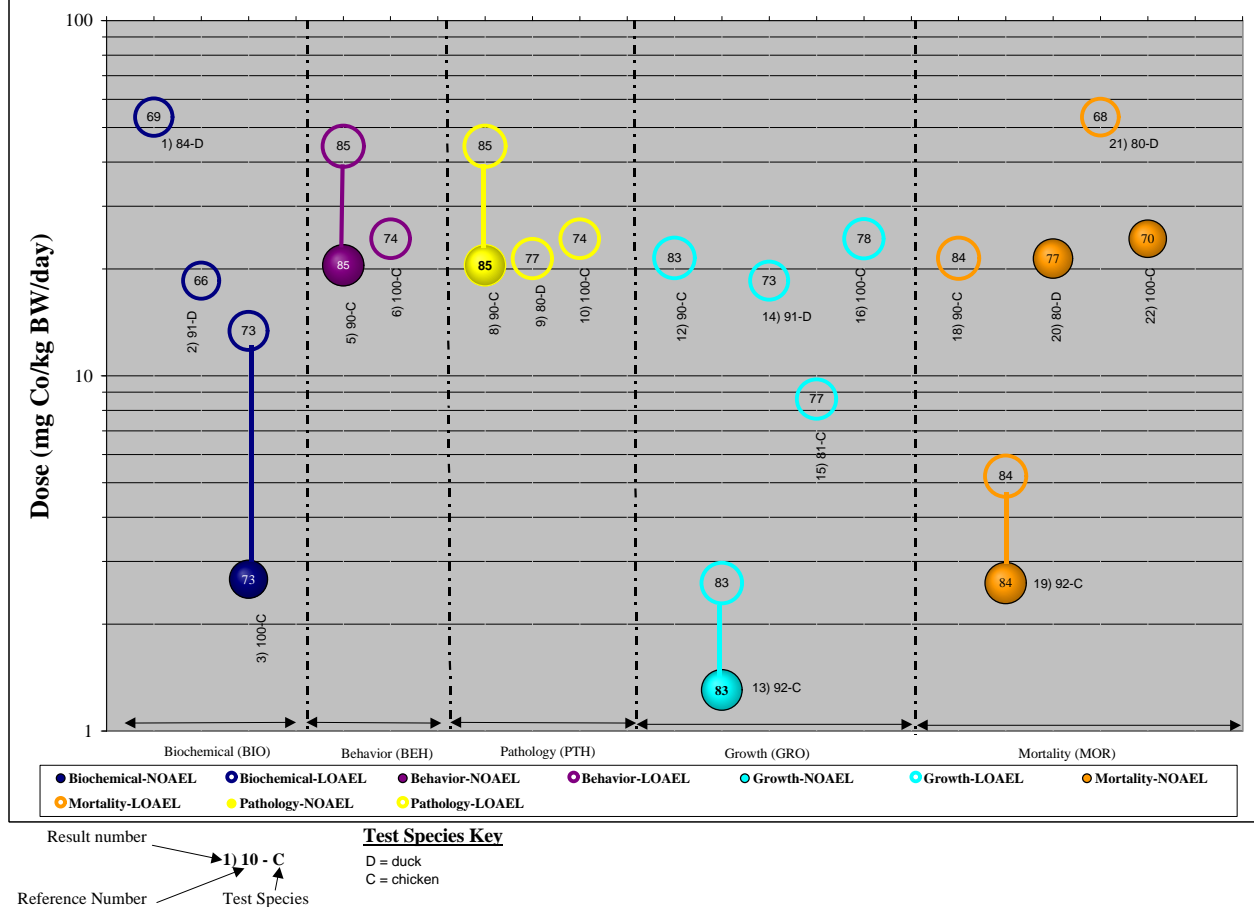
#### **4.4 Avian Cobalt TRV**

The NOAEL and LOAEL values for results with data evaluation scores above 65 are plotted on Figure 4.2 for cobalt. The following steps were completed to identify a TRV.

- 1) There are at least three results available for growth (GRO), reproduction (REP) or mortality (MOR) endpoints for at least two test species. There is enough data to derive a TRV.
- 2) There are less than three NOAEL results available for GRO or REP. There is not enough data to calculate a weighted geometric mean.
- 3) There is at least one NOAEL result available for growth (GRO).
- 4) The NOAEL for growth at 1.3 mg Co/kg BW/day is less than the lowest LOAEL for mortality.
- 5) The NOAEL of 1.3 mg Co/kg BW/day is the avian TRV for cobalt.



**Figure 4.2 Avian TRV Derivation for Cobalt**



#### Wildlife TRV Derivation Process

- 1) There are at least three results available for two test species within the GRO, REP and MOR effect groups.  
There is enough data to derive TRV.
- 2) There are less than three NOAEL results available within either the GRO, REP or MOR effect groups.  
A weighted geometric mean cannot be calculated.
- 3) There is at least one NOAEL result available for growth (GRO)
- 4) The NOAEL for growth at 1.3 mg Co/kg BW/ day is less than the lowest LOAEL for mortality.
- 5) The NOAEL of 1.3 mg Co/kg BW/day is the avian TRV for cobalt.

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## **5.0 DIELDRIN**

### **5.1 Literature Search, Retrieval and Review**

The electronic literature search for dieldrin toxicity data was completed according to the procedures provided in Exhibit 4-1. The search results are reported as four separate lists. The first list contains studies identified during the electronic search that were rejected for use based on a review of the abstract and title. This list is included as Attachment A to this appendix. The second list reports the literature for which useful toxicological data was identified and extracted (literature used). The third list reports the literature that was retrieved, reviewed and then rejected (literature rejected). The fourth list contains literature identified in the search that either could not be retrieved for review or has not been received for review (literature pending). These references are listed as Section 5.5.

Each of the citations in these lists are identified with a unique record number assigned as part of the data extraction process as described in Appendix 4-3 (SOP #2). Citations on the “literature not coded” list are labeled with respective literature rejection criteria also described in Appendix 4-3 (SOP #2).

### **5.2 Data Review and Evaluation**

The electronic and manual literature search process (Exhibit 4-1) for dieldrin identified 276 studies. Of these, 101 studies contained data extracted and used to derive the Eco-SSL, 151 studies were rejected for use and 24 studies are pending receipt for review.

#### ***Mammalian Data***

Data was extracted from thirty-nine studies for derivation of the mammalian TRV for dieldrin. The data reviewed and extracted from these studies is summarized in Table 5.1.

#### ***Avian Data***

Data was extracted from the thirty-four studies for derivation of the avian dieldrin TRV. The data reviewed and extracted from these studies is summarized in Table 5.2.

### **5.3 Mammalian Dieldrin TRV**

The NOAEL and LOAEL values for results with data evaluation scores above 65 are plotted on Figure 5.1 for dieldrin. The following steps were completed to identify a TRV.

- 1) There are at least three results available for growth (GRO), reproduction (REP) or mortality (MOR) endpoints for at least two test species. There is enough data to derive a TRV.

Table 5.1 Mammalian Toxicity Data for Dieldrin

TEST INFORMATION			EXPOSURE INFORMATION										EFFECT INFORMATION							DATA EVALUATION SCORES									
Result #	Test ID	Species	# of Conc/ Doses	Reported Conc/Dose Units	Method of Analyses	Route of Exposure	Exposure Duration	Duration Units	Age	Age Units	Lifespan	Sex	General Effect Group	Effect Type	Effect Measure	Response Site	NOAEL Dose (mg/kg/day)	LOAEL Dose (mg/kg/day)	Data Source	Dose Route	Test Substance	Chemical form	Dose Quantification	Endpoint	Dose Range	Statistical Power	Exposure Duration	Test Conditions	Total
1	1146-Dld-Walke-ML-OR-2-BIO-3	dog	3	mg/kg/d	M	OR	104	w	5.5	mo	NR	BH	BIO	CHM	TOPR	SR	0.005	0.05	10	8	10	10	10	1	8	10	10	4	81
2	1146-Dld-Walke-ML-OR-2-BIO-1	dog	3	mg/kg/d	M	OR	104	w	5.5	mo	NR	BH	BIO	ENZ	ALPH	PL	0.005	0.05	10	8	10	10	10	1	8	10	10	4	81
3	1146-Dld-Walke-ML-OR-2-BIO-2	dog	3	mg/kg/d	M	OR	104	w	5.5	mo	NR	BH	BIO	CHM	HMGL	BL	0.05		10	8	10	10	10	1	4	1	10	4	68
4	1146-Dld-Walke-ML-OR-2-BIO-4	dog	3	mg/kg/d	M	OR	104	w	5.5	mo	NR	BH	BIO	ENZ	CEST	ER	0.05		10	8	10	10	10	1	4	1	10	4	68
5	1122-Dld-Sieve-ML-FD-1-BIO-6	mouse	4	mg/kg	U	FD	28	d	4	w	NR	M	BIO	ENZ	EROD	LI	0.127	0.3812	10	10	5	10	5	1	10	10	6	4	71
6	1139-Dld-van R-ML-FD-1-BIO-1	mouse	4	ppm	U	FD	14	mo	4.5	w	JV	F	BIO	ENZ	AATT	LI	0.13	0.64	10	10	5	10	5	1	8	10	10	4	73
7	1056-Dld-Murph-ML-FD-1-BIO-7	deer	3	mg/kg BW/day	U	FD	3	y	1	y	MU	F	BIO	ENZ	ALPH	SR	0.14	0.69	10	10	5	10	10	1	8	10	10	4	78
8	1026-Dld-Kramp-ML-GV-1-BIO-3	rat	5	mg/kg	M	GV	13	d	NR	NR	NR	M	BIO	ENZ	Other	LI	0.25	1.25	10	8	10	10	10	1	8	10	6	4	77
9	1146-Dld-Walke-ML-FD-1-BIO-5	rat	4	ppm	M	FD	104	w	5	w	NR	BH	BIO	CHM	HMGL	BL	0.79		10	10	10	10	6	1	4	10	2	73	
10	1146-Dld-Walke-ML-FD-1-BIO-6	rat	4	ppm	M	FD	104	w	5	w	NR	BH	BIO	ENZ	ALPH	PL	0.79		10	10	10	10	6	1	4	10	2	73	
11	998-Dld-Hurka-ML-GV-1-BIO-4	rat	2	mg/kg/2 d	M	GV	100	d	NR	NR	NR	NR	BIO	ENZ	ALPH	LI	2.5		10	8	10	10	10	1	4	1	10	4	68
12	961-Dld-Foste-ML-FD-1-BIO-1	rat	3	ppm	U	FD	6	w	NR	NR	NR	M	BIO	HRM	CORT	AR	9.8	19.6	10	10	5	10	7	1	10	10	6	4	73
13	1026-Dld-Kramp-ML-GV-1-BIO-4	rat	5	mg/kg	M	GV	13	d	NR	NR	NR	NR	BIO	ENZ	PNAD	LI		0.05	10	8	10	10	10	1	4	10	6	4	73
14	1141-Dld-Virgo-ML-FD-1-BIO-2	mouse	5	ppm	U	FD	10	w	13	w	NR	F	BIO	CHM	TOPR	MC		0.64	10	10	5	10	5	1	4	10	10	4	69
15	1040-Dld-Mehro-ML-FD-1-BIO-5	rat	2	ppm	U	FD	60	d	NR	NR	NR	M	BIO	ENZ	Other	BR		0.92	10	10	5	10	6	1	4	10	6	4	66
16	999-Dld-Hurka-ML-GV-1-BIO-4	rabbit	2	mg/kg/d	M	GV	100	d	NR	NR	NR	NR	BIO	CHM	CHOL	LI	1.25		10	8	10	10	10	1	4	10	6	4	73
17	999-Dld-Hurka-ML-GV-1-BIO-5	rabbit	2	mg/kg/d	M	GV	100	d	NR	NR	NR	NR	BIO	ENZ	ALPH	LI	1.25		10	8	10	10	10	1	4	10	6	4	73
18	998-Dld-Hurka-ML-GV-1-BIO-3	rat	2	mg/kg/2 d	M	GV	100	d	NR	NR	NR	NR	BIO	CHM	GLYC	LI	2.5		10	8	10	10	10	1	4	10	10	4	77
19	1163-Dld-Zemai-ML-FD-1-BIO-1	rat	2	ppm	U	FD	8	w	NR	NR	MA	F	BIO	ENZ	CEST	PL		5	10	10	5	10	6	1	4	10	6	4	66
20	911-Dld-Bandy-ML-GV-1-BIO-5	rat	2	mg/kg/d	M	GV	15	d	NR	NR	YO	M	BIO	CHM	Other	LI		5	10	8	10	10	10	1	4	10	6	4	73
21	911-Dld-Bandy-ML-GV-1-BIO-4	rat	2	mg/kg/d	M	GV	15	d	NR	NR	YO	M	BIO	ENZ	Other	LI		5	10	8	10	10	10	1	4	10	6	4	73
22																													
23	1056-Dld-Murph-ML-FD-1-BEH-1	deer	3	mg/kg BW/day	U	FD	3	y	1	y	MU	F	BEH	FDB	FCNS	WO	0.69		10	10	5	10	10	4	4	1	10	4	68
24	1146-Dld-Walke-ML-FD-1-BEH-3	rat	4	ppm	M	FD	104	w	5	w	NR	BH	BEH	FDB	FCNS	WO	0.79		10	10	10	10	6	4	4	1	10	2	67
25	988-Dld-Harr -ML-FD-1-BEH-3	rat	11	ppm	M	FD	400	d	28	d	NR	BH	BEH	FDB	FCNS	WO	0.85	1.7	10	10	10	10	7	4	10	10	4	85	
26	1023-Dld-Kolaj-ML-FD-1-BEH-3	mouse	5	mg/kg	M	FD	90	d	8	w	NR	M	BEH	FDB	FCNS	WO	1.27		10	10	10	10	5	4	4	1	10	7	71
27	1023-Dld-Kolaj-ML-FD-2-BEH-1	rat	5	mg/kg	M	FD	90	d	8	w	NR	M	BEH	FDB	FCNS	WO	1.27		10	10	10	10	5	4	4	1	10	7	71
28	918-Dld-Bids-ML-FD-1-BEH-2	mouse	2	ppm	U	FD	3	mo	3.5	mo	NR	NR	BEH	BEH	FRZG	WO		1.3	10	10	5	10	5	4	4	10	10	4	72
29	1141-Dld-Virgo-ML-FD-1-BEH-3	mouse	5	ppm	U	FD	10	w	13	w	NR	F	BEH	BEH	INST	WO		0.64	10	10	5	10	5	4	4	10	10	4	72
30	1020-Dld-Kimbr-ML-FD-1-BEH-3	rat	3	mg/kg BW/day	U	FD	8	w	3.5	mo	AD	M	BEH	BEH	INST	WO		2.64	10	10	5	10	10	4	4	10	6	4	73
31	1040-Dld-Mehro-ML-FD-1-BEH-3	rat	2	ppm	U	FD	60	d	NR	NR	NR	M	BEH	FDB	FCNS	WO		0.92	10	10	5	10	6	4	4	10	6	4	69
32																													
33	1056-Dld-Murph-ML-FD-1-PHY-10	deer	3	mg/kg BW/day	U	FD	3	y	1	y	MU	F	PHY	PHY	OTHR	KI	0.69		10	10	5	10	10	4	4	1	10	4	68
34																													
35	1146-Dld-Walke-ML-OR-2-PTH-8	dog	3	mg/kg/d	M	OR	104	w	5.5	mo	NR	M	PTH	ORWT	ORWT	SP	0.005	0.05	10	8	10	10	10	4	8	10	10	4	84
36	1026-Dld-Kramp-ML-GV-1-PTH-1	rat	5	mg/kg	M	GV	13	d	NR	NR	NR	M	PTH	ORWT	SMIX	LI	0.05	0.25	10	8	10	10	10	4	8	10	6	4	80
37	1146-Dld-Walke-ML-OR-2-PTH-6	dog	3	mg/kg/d	M	OR	104	w	5.5	mo	NR	BH	PTH	ORWT	ORWT	KI	0.05		10	8	10	10	10	4	4	3	10	4	73
38	1146-Dld-Walke-ML-FD-1-PTH-1	rat	4	ppm	M	FD	104	w	5	w	NR	BH	PTH	HIS	GLSN	KI	0.082	0.79	10	10	10	10	6	4	8	10	10	4	82
39	1122-Dld-Sieve-ML-FD-1-PTH-4	mouse	4	mg/kg	U	FD	28	d	4	w	NR	M	PTH	HIS	GHIS	LI	0.127	0.3812	10	10	5	10	5	4	10	10	6	4	74
40	1023-Dld-Kolaj-ML-FD-1-PTH-1	mouse	5	mg/kg	M	FD	90	d	8	w	NR	M	PTH	ORWT	SMIX	LI	0.127	0.3812	10	10	10	10	5	4	10	10	7	86	
41	1056-Dld-Murph-ML-FD-1-PTH-8	deer	3	mg/kg BW/day	U	FD	3	y	1	y	MU	F	PTH	ORWT	ORWT	LI	0.14	0.69	10	10	5	10	10	4	8	10	10	4	81
42	960-Dld-Fitzh-ML-FD-1-PTH-3	rat	7	ppm	U	FD	2	y	NR	NR	JV	M	PTH	ORWT	SMIX	LI	0.16	0.79	10	10	5	10	6	4	8	10	10	4	77
43	1122-Dld-Sieve-ML-FD-1-PTH-2	mouse	4	mg/kg	U	FD	28	d	4	w	NR	M	PTH	ORWT	SMIX	LI	0.3812	1.27	10	10	5	10	5	4	8	10	6	4	72
44	1139-Dld-van R-ML-FD-1-PTH-2	mouse	4	ppm	U	FD	14	mo	4.5	w	JV	F	PTH	HIS	GLSN	LI	0.64	1.3	10	10	5	10	5	4	8	10	10	4	76
45	1056-Dld-Murph-ML-FD-1-PTH-9	deer	3	mg/kg BW/day	U	FD	3	y	1	y	MU	F	PTH	ORWT	ORWT	KI	0.69		10	10	5	10	10	4	4	1	10	4	68
46	1146-Dld-Walke-ML-FD-1-PTH-7	rat	4	ppm	M	FD	104	w	5	w	NR	BH	PTH	ORWT	ORWT	BR	0.79		10	10	10	10	6	4	4	10	10	2	76
47	1096-Dld-Reube-ML-FD-1-PTH-2	rat	8	ppm	U	FD	2	y	3	w	NR	BH	PTH	HIS	NPHR	KI	0.79	3.96	10	10	5	10	5	4	8	10	10	4	76
48	960-Dld-Fitzh-ML-FD-1-PTH-4	rat	7	ppm	U	FD	2	y	NR	NR	JV	BH	PTH	HIS	GHIS	LI	0.80	4.1	10	10	5	10	6	4					

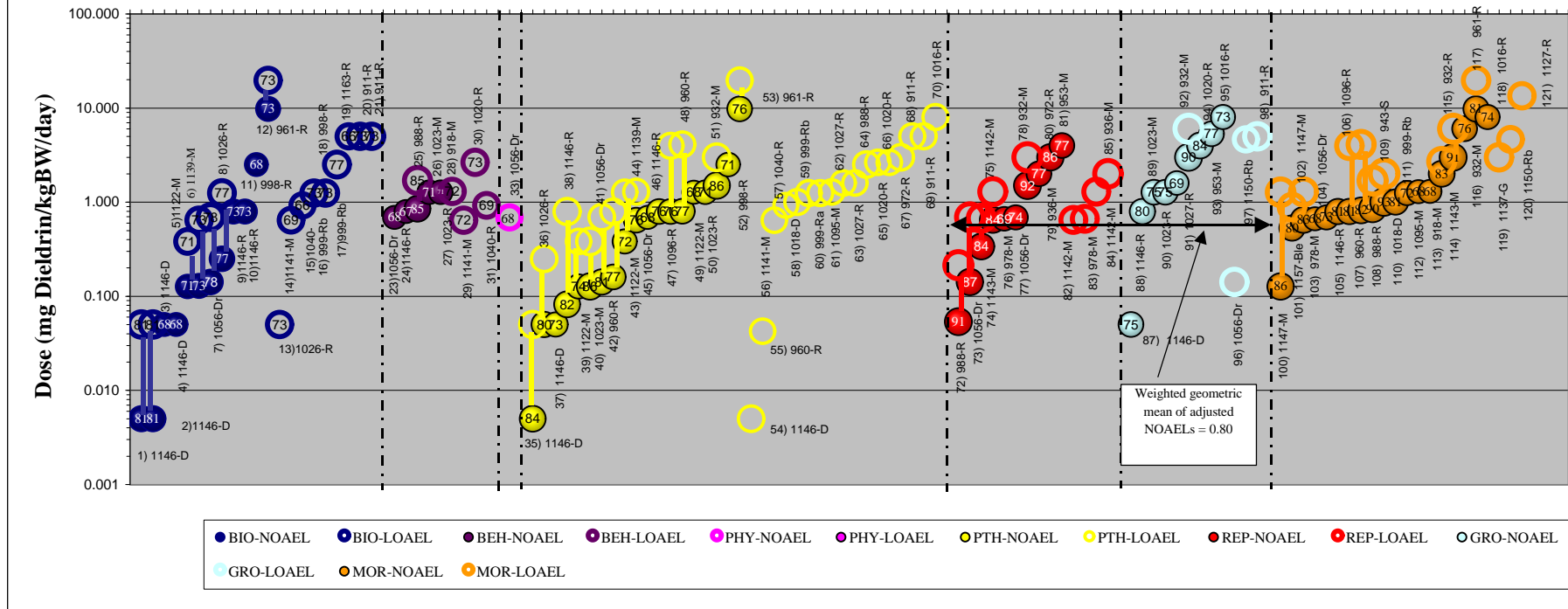
Table 5.1 Mammalian Toxicity Data for Dieldrin

TEST INFORMATION		EXPOSURE INFORMATION										EFFECT INFORMATION						DATA EVALUATION SCORES											
Result #	Test ID	Species	# of Conc/ Doses	Reported Conc/Dose Units	Method of Analyses	Route of Exposure	Exposure Duration	Duration Units	Age	Age Units	Lifespan	Sex	General Effect Group	Effect Type	Effect Measure	Response Site	NOAEL Dose (mg/kg/day)	LOAEL Dose (mg/kg/day)	Data Source	Dose Route	Test Substance	Chemical form	Dose Quantification	Endpoint	Dose Range	Statistical Power	Exposure Duration	Test Conditions	Total
94	1020-Dld-Kimbr-ML-FD-1-GRO-1	rat	3	ppm	U	FD	8	w	3.5	mo	AD	M	GRO	GRO	BDWT	WO	5.33		10	10	5	10	10	8	4	10	6	4	77
95	1016-Dld-Jones-ML-FD-1-GRO-2	rat	2	mg/kg/day	M	FD	8	w	5	y	NR	BH	GRO	GRO	BDWT	WO	8.00		10	10	10	10	10	8	4	1	6	4	73
96	1056-Dld-Murph-ML-FD-1-GRO-5	deer	3	mg/kg BW/day	U	FD	3	y	1	y	MU	F	GRO	GRO	BDWT	WO		0.14	10	10	5	10	10	8	4	10	10	4	81
97	1150-Dld-Wasse-ML-DR-1-GRO-1	rabbit	2	ppm	M	DR	5	w	NR	NR	YO	M	GRO	GRO	BDWT	WO		4.6	10	5	5	10	6	8	4	10	6	4	68
98	911-Dld-Bandy-ML-GV-1-GRO-3	rat	2	mg/kg/d	M	GV	15	d	NR	NR	YO	M	GRO	GRO	BDWT	WO		5	10	8	10	10	10	8	4	10	6	4	80
99																													
100	1147-Dld-Walke-ML-FD-1-MOR-1	mouse	4	ppm	M	FD	132	w	3	w	MU	BH	MOR	MOR	MORT	WO	0.13	1.3	10	10	10	10	5	9	8	10	10	4	86
101	1157-Dld-Wiese-ML-FD-1-MOR-1	blesback	6	ppm	U	FD	90	d	1	y	NR	BH	MOR	MOR	MORT	WO	0.53	0.89	10	10	5	10	6	9	10	10	6	4	80
102	1147-Dld-Walke-ML-FD-2-MOR-1	mouse	6	ppm	U	FD	128	w	3	w	MU	BH	MOR	MOR	MORT	WO	0.65	1.3	10	10	5	10	5	9	10	10	10	4	83
103	978-Dld-Good -ML-FD-1-MOR-1	mouse	2	ppm	U	FD	120	d	6	w	NR	BH	MOR	MOR	MORT	WO	0.66		10	10	5	10	5	9	4	1	10	4	68
104	1056-Dld-Murph-ML-FD-1-MOR-2	deer	3	mg/kg BW/day	U	FD	3	y	1	y	MU	F	MOR	MOR	MORT	WO	0.69		10	10	5	10	10	9	4	1	10	4	73
105	1146-Dld-Walke-ML-FD-1-MOR-4	rat	4	ppm	M	FD	104	w	5	w	MU	BH	MOR	MOR	MORT	WO	0.79		10	10	10	10	6	9	4	10	10	2	81
106	1096-Dld-Reube-ML-FD-1-MOR-1	rat	8	ppm	U	FD	2	y	3	w	NR	BH	MOR	MOR	MORT	WO	0.79	3.95	10	10	5	10	5	9	8	10	10	4	81
107	960-Dld-Fitzh-ML-FD-1-MOR-1	rat	7	ppm	U	FD	2	y	NR	NR	JV	BH	MOR	MOR	SURV	WO	0.82	4.1	10	10	5	10	6	9	8	10	10	4	82
108	988-Dld-Harr -ML-FD-1-MOR-2	rat	11	ppm	M	FD	400	d	28	d	MU	BH	MOR	MOR	MORT	WO	0.85	1.7	10	10	10	10	7	9	10	10	10	4	90
109	943-Dld-Davis-ML-FD-1-MOR-1	sheep	5	mg/kg	M	FD	32	w	NR	NR	NR	M	MOR	MOR	MORT	WO	1	2	10	10	10	10	10	9	10	10	10	4	93
110	1018-Dld-Keane-ML-OR-1-MOR-2	dog	3	mg/kg/d	M	OR	85	d	25.5	mo	AD	NR	MOR	MOR	MORT	WO	1		10	8	10	10	10	9	4	10	6	4	81
111	999-Dld-Hurka-ML-GV-1-MOR-3	rabbit	2	mg/kg/d	M	GV	100	d	NR	NR	NR	NR	MOR	MOR	MORT	WO	1.25		10	8	10	10	10	9	4	1	6	4	72
112	1095-Dld-Reube-ML-FD-1-MOR-1	mouse	2	ppm	U	FD	104	w	3	w	NR	BH	MOR	MOR	MORT	WO	1.3		10	10	5	10	5	9	4	1	10	4	68
113	918-Dld-Bilds-ML-FD-1-MOR-1	mouse	2	ppm	U	FD	3	mo	3.5	mo	NR	NR	MOR	MOR	MORT	WO	1.3		10	10	5	10	5	9	4	1	10	4	68
114	1143-Dld-Virgo-ML-FD-1-MOR-3	mouse	7	ppm	U	FD	13	w	5	w	SM	F	MOR	MOR	SURV	WO	2	2.7	10	10	5	10	5	9	10	10	10	4	91
115	932-Dld-Chern-ML-GV-2-MOR-1	rat	4	mg/kg/d	M	GV	10	d	NR	NR	SM	F	MOR	MOR	MORT	WO	3	6	10	8	10	10	10	9	10	10	10	4	83
116	932-Dld-Chern-ML-GV-1-MOR-3	mouse	4	mg/kg/d	M	GV	10	d	NR	NR	SM	F	MOR	MOR	MORT	WO	6		10	8	10	10	10	9	4	1	10	4	76
117	961-Dld-Foste-ML-FD-1-MOR-3	rat	3	ppm	U	FD	6	w	NR	NR	NR	M	MOR	MOR	MORT	WO	9.8	19.6	10	10	5	10	7	9	10	10	6	4	81
118	1016-Dld-Jones-ML-FD-1-MOR-1	rat	2	mg/kg/day	M	FD	8	w	5	w	NR	BH	MOR	MOR	MORT	WO	8.00		10	10	10	10	10	9	4	1	6	4	74
119	1137-Dld-Uzouk-ML-OR-1-MOR-1	guinea pig	2	mg/kg/ 5 d	M	OR	75	d	NR	NR	NR	F	MOR	MOR	MORT	WO		3	10	8	10	10	10	9	4	10	6	4	81
120	1150-Dld-Wasse-ML-DR-1-MOR-3	rabbit	2	ppm	M	DR	5	w	NR	NR	YO	M	MOR	MOR	MORT	WO		4.6	10	5	5	10	6	9	4	10	6	4	69
121	1127-Dld-Stoew-ML-FD-1-MOR-1	rat	2	ppm	U	FD	42	d	NR	NR	JV	BH	MOR	MOR	MORT	WO		13.5	10	10	5	10	5	9	4	10	6	4	73
122																													

Table 5.2 Avian Toxicity for Dieldrin

TEST INFORMATION		SURE INFORMATION				EFFECTS INFORMATION												DATA EVALUATION SCORES													
Result #	Reference Number	Test ID	Species	# of Conc/ Doses	Reported Conc/Dose Units	Method of Analyses	Route of Exposure	Exposure Duration	Duration Units	Age	Age Units	Lifespan	Sex	Effect Group	Effect Type	Effect Measure	Response Site	NOAEL Dose (mg/kg/day)	LOAEL Dose (mg/kg/day)	Data Source	Dose Route	Test Concentrations	Chemical form	Dose Quantification	Endpoint	Dose Range	Statistical Power	Exposure Duration	Test Conditions	Total	
1	990	990-Dld-Heinz-AV-FD-1-BIO-5	Ring dove	4	mg/kg diet	M	FD	8	w	NR	NR	AD	BH	BIO	HRM	DOPA	BR	0.09	0.32	10	10	10	10	6	1	8	10	6	4	75	
2	1109	1109-Dld-Sharm-AV-FD-1-BIO-3	Mallard	4	mg/kg diet	U	FD	2	m	0	d	JV	BH	BIO	CHM	SRTN	BR	0.23	0.57	10	10	5	10	5	1	10	10	4	75		
3	1110	1110-Dld-Sharm-AV-FD-1-BIO-1	Mallard	4	ppm	U	FD	75	d	NR	NR	MU	BH	BIO	CHM	SRTN	BR	0.24	0.61	10	10	5	10	6	1	10	10	2	74		
4	40	40-Dld-Davis-AV-FD-1-BIO-4	Mallard	4	ppm	U	FD	48	w	2	y	MA	F	BIO	ENZ	AHDX	LI	0.54		10	10	5	10	5	1	4	10	4	69		
5	1106	1106-Dld-Sell-AV-FD-1-BIO-5	Quail	3	mg/kg	U	FD	28	w	28	w	SM	F	BIO	CHM	P450	LI	0.56	1.13	10	10	5	10	7	1	10	10	4	77		
6	1109	1109-Dld-Sharm-AV-FD-1-BIO-4	Mallard	4	mg/kg	U	FD	2	m	0	d	JV	BH	BIO	HRM	DOPA	BR	0.57	1.70	10	10	5	10	5	1	10	10	4	75		
7	1110	1110-Dld-Sharm-AV-FD-1-BIO-5	Mallard	4	ppm	U	FD	75	d	NR	NR	MU	BH	BIO	BIO	ENZ	LI	0.61	1.82	10	10	5	10	6	1	10	10	2	74		
8	40	40-Dld-Davis-AV-FD-1-BIO-2	Mallard	4	ppm	U	FD	48	w	2	y	MA	F	BIO	CHM	P450	LI		1.9	10	10	5	10	6	1	10	10	4	76		
9	990	990-Dld-Heinz-AV-FD-1-BIO-7	Ring dove	4	mg/kg	M	FD	8	w	NR	NR	AD	BH	BIO	CHM	HMCT	BL	0.97		10	10	10	10	6	1	4	10	6	4	71	
10	1106	1106-Dld-Sell-AV-FD-1-BIO-2	Quail	3	mg/kg	U	FD	28	w	28	w	SM	F	BIO	CHM	GLYC	LI	1.13		10	10	5	10	7	1	4	10	4	71		
11	1109	1109-Dld-Sharm-AV-FD-1-BIO-2	Mallard	4	mg/kg	U	FD	2	m	0	d	JV	BH	BIO	CHM	TOPR	BR	1.7		10	10	5	10	5	1	4	10	4	69		
12	908	908-Dld-Anduj-AV-FD-1-BIO-2	Quail	3	ppm	U	FD	48	d	NR	NR	AD	BH	BIO	CHM	CALC	PL	2.7		10	10	5	10	5	1	4	10	4	69		
13	930	930-Dld-Call-AV-FD-1-BIO-1	Quail	5	mg/kg	U	FD	14	d	7	w	JV	BH	BIO	BIO	CHM	CALC	10.11		10	10	5	10	5	1	4	10	4	69		
14	930	930-Dld-Call-AV-FD-1-BIO-2	Quail	5	mg/kg	U	FD	14	d	7	w	JV	BH	BIO	CHM	CHM	LIPD		0.67	10	10	5	10	5	1	4	10	4	69		
15	975	975-Dld-Gille-AV-FD-1-BIO-3	Quail	2	mg/kg	U	FD	35	d	7	d	JV	BH	BIO	ENZ	AEPX	LI		2.09	10	10	5	10	7	1	4	10	4	71		
16	908	908-Dld-Anduj-AV-FD-1-BIO-1	Quail	2	ppm	U	FD	48	d	NR	NR	AD	BH	BIO	CHM	CALC	EG		2.67	10	10	5	10	5	1	4	10	4	69		
17																															
18	909	909-Dld-Atkin-AV-OR-2-BEH-1	Pheasant	3	mg/hen/week	M	OR	12	w	11	m	SM	F	BEH	FDB	FCNS	WO	0.220	0.44	10	8	10	10	6	4	10	10	4	82		
19	909	909-Dld-Atkin-AV-OR-1-BEH-1	Pheasant	3	mg/hen/week	M	OR	12	w	11	m	SM	F	BEH	FDB	FCNS	WO	0.6		10	8	10	10	6	4	3	10	4	69		
20	942	942-Dld-Davis-AV-FD-1-BEH-3	Mallard	4	ppm	M	FD	48	w	2	y	AD	F	BEH	FDB	FCNS	WO	0.93		10	10	10	10	7	4	4	1	10	4	70	
21	990	990-Dld-Heinz-AV-FD-1-BEH-1	Ring dove	4	mg/kg	M	FD	8	w	NR	NR	AD	BH	BIO	BEH	FDB	FCNS	WO	0.97		10	10	10	10	6	4	4	1	10	4	74
22	974	974-Dld-Gesel-AV-OR-1-BEH-1	Quail	6	ug/2days	M	OR	28	d	NR	NR	AD	M	BEH	BEH	NVOC	WO		0.14	10	8	10	10	5	4	4	10	6	4	71	
23	1110	1110-Dld-Sharm-AV-FD-1-BEH-2	Mallard	4	ppm	U	FD	75	d	NR	NR	MU	BH	BEH	BEH	BHVR	WO		0.24	10	10	5	10	6	4	4	10	10	2	71	
24	928	928-Dld-Busbe-AV-GV-1-BEH-1	Loggerhead shrike	5	mg/kgBW/day	U	GV	58	d	NR	NR	JV	BH	BEH	FDB	FEFF	WO		1.0	10	8	5	10	10	4	4	10	10	4	75	
25																															
26	1158	1158-Dld-Wiese-AV-FD-1-PTH-2	Guinea fowl	7	ppm	U	FD	21	m	NR	NR	NR	BH	PTH	ORWT	ORWT	LI	0.30	0.89	10	10	5	10	7	4	10	10	4	80		
27	990	990-Dld-Heinz-AV-FD-1-PTH-3	Ring dove	4	mg/kg	M	FD	8	w	NR	NR	AD	BH	PTH	ORWT	ORWT	LI	0.32	0.97	10	10	10	10	6	4	8	10	6	4	78	
28	40	40-Dld-Davis-AV-FD-1-PTH-5	Mallard	4	ppm	U	FD	48	w	2	y	MA	F	PTH	ORWT	ORWT	LI	0.57		10	10	5	10	5	4	4	10	4	72		
29	1110	1110-Dld-Sharm-AV-FD-1-PTH-4	Mallard	4	ppm	U	FD	75	d	NR	NR	MU	BH	PTH	ORWT	SMIX	BR	0.61	1.82	10	10	5	10	6	4	10	10	2	77		
30	926	926-Dld-Brown-AV-FD-1-PTH-5	Chicken	3	mg/kg	U	FD	13	m	6	w	JV	BH	PTH	HIS	GLSN	LI	0.93		10	10	5	10	6	4	4	1	10	10	70	
31	1010	1010-Dld-Jeffe-AV-OR-1-PTH-2	Pigeon	4	mg/kgBW/day	M	OR	8	w	NR	NR	NR	BH	PTH	ORWT	ORWT	TY	1.0	4.0	10	8	10	10	10	4	8	10	6	4	80	
32	1106	1106-Dld-Sell-AV-FD-1-PTH-1	Quail	3	mg/kg	U	FD	28	w	28	w	SM	F	PTH	ORWT	ORWT	LI	1.13		10	10	5	10	7	4	4	10	10	4	74	
33	1109	1109-Dld-Sharm-AV-FD-1-PTH-1	Mallard	4	mg/kg	U	FD	2	m	0	d	JV	BH	PTH	ORWT	ORWT	BR	1.7		10	10	5	10	5	4	4	10	4	72		
34	1010	1010-Dld-Jeffe-AV-OR-1-PTH-4	Pigeon	4	mg/kgBW/day	M	OR	8	w	NR	NR	NR	BH	PTH	ORWT	ORWT	AR	4.0		10	8	10	10	10	4	4	1	6	4	67	
35	1010	1010-Dld-Jeffe-AV-OR-1-PTH-3	Pigeon	4	mg/kgBW/day	M	OR	8	w	NR	NR	NR	BH	PTH	HIS	GHIS	TY		1.0	10	8	10	10	10	4	4	10	6	4	76	
36																															
37	1042	1042-Dld-Mend-AV-FD-1-REP-2	Barn owl	2	ppm	U	FD	2	y	5	m	JV	BH	REP	EGG	EGWT	WO	0.042		10	10	10	10	5	9	4	1	10	10	79	
38	1130	1130-Dld-Strom-AV-FD-1-REP-2	Pheasant	2	mg/kg	U	FD	42	d	1	y	AD	F	REP	REP	REP	WO	0.059		10	10	5	10	6	10	4	1	10	4	70	
39	1111	1111-Dld-Shell-AV-FD-1-REP-3	Quail	3	ppm	U	FD	3	lf	3-5	d	AD	BH	REP	REP	RSUC	WO	0.145		10	10	5	10	6	10	4	1	10	2	68	
40	909	909-Dld-Atkin-AV-OR-2-REP-6	Pheasant	3	mg/hen/week	M	OR	12	w	11	m	SM	F	REP	EGG	EGWT	WO	0.439	0.659	10	8	10	10	6	10	10	10	4	88		
41	942	942-Dld-Davis-AV-FD-1-REP-6	Mallard	4	ppm	M	FD	48	w	2	y	AD	F	REP	EGG	ESWT	EG	0.47	0.93	10	10	10	10	7	10	10	10	4	91		
42	909	909-Dld-Atkin-AV-OR-1-REP-4	Pheasant	3	mg/hen/week	M	OR	12	w	11	m	SM	F	REP	EGG	FTEG	WO	0.555		10	8	10	10	6	10	4	1	10	4	73	
43	40	40-Dld-Davis-AV-FD-1-REP-6	Mallard	4	ppm	U	FD	48	w	2	y	MA	F	REP	REP	EGPN	WO	0.57		10	10	5	10	5	10	4	1	10	4	69	
44	1092	1092-Dld-Readi-AV-FD-2-REP-6	Quail	3	ppm	U	FD	16	w	5 to 6	w	SM	BH	REP	REP	RSUC	WO	0.595		10	10	5	10	6	10	10	10	4	85		
45	909	909-Dld-Atkin-AV-OR-2-REP-5	Pheasant	3	mg/hen/week	M	OR	12	w	11	m	SM	F	REP	EGG	FTEG	WO	0.659		10	8	10	10	6	10	4	1	10	4	73	
46	1158	1158-Dld-Wiese-AV-FD-1-REP-4	Guinea fowl	7	ppm	U	FD	21	m	NR	NR	NR	BH	REP	EGG	EGWT	WO	0.89		10	10	5	10	7	10	4	1	10	4	71	
47	926	926-Dld-Brown-AV-FD-1-REP-4	Chicken	3	mg/kg	U	FD	13	m	6	w	JV	BH	REP	EGG	ESWT	EG	0.93		10	10	5	10	6	10	4	1	10	10	76	
48	942	942-Dld-Davis-AV-FD-1-REP-5	Chicken	4	ppm	M	FD	48	w	2	y	AD	F	REP	EGG	CREG	EG	0.93		10	10	10	10	7	10	4	1	10	4	69	
49	944	944-Dld-Davis-AV-FD-1-REP-2	Chicken	3	ppm	U	FD	12	w	28	w	SM	F	REP	REP	EGWT	WO	1.1		10	10	5	10	7	10	4	1	10	2	69	
48	941	941-Dld-Dallie-AV-OR-1-REP-1	Pheasant	4	mg/hen/week	M	OR	16	w	NR	NR	SM	F	REP	EGG	ESTH	WO	1.50		10	8	10	10	6	10	4	10	4	82		
49	995	995-Dld-Hill-AV-FD-1-REP-1	Quail	2	mg/kg	U	FD	20	w				SM	M	REP	REP	SPCL	WO	1.70		10	10	5	10	7	10	10	6	4	76	
50	995	995-Dld-Hill-AV-FD-1-REP-3	Quail	4	mg/kg	U	FD	75	d	6	m	SM	F	REP	EGG	ESTH	EG	2.1		10	10	5	10	5	10	4	10	4	78		
51	908	908-Dld-Anduj-AV-FD-1-REP-4	Quail	3	ppm	U	FD	48	d	NR	NR	AD	BH	REP	EGG	EGWT	EG	2.7		10	10	5	10	5	10	4	1	10	4	69	
52	1092	1092-Dld-Readi-AV-FD-1-REP-5	Quail	3	ppm	U	FD	24	w	5 to 6	w	SM	F	REP	REP	FERT	WO	3.0		10	10	5	10	6	10	4	1	10	4	70	
53	1158	1158-Dld-Wiese-AV-FD-1-REP-3	Guinea fowl	7	ppm	U	FD	21	m	NR	NR	NR	BH	REP	REP	PRWT	WO	0.89		10	10	5	10	7	10	4	10	10	4	80	

Figure 5.1 Mammalian TRV Derivation for Dieldrin



Result number → 1) 10 - C  
Reference Number → Test Species

**Test Species Key**

D = dog  
R = rat  
M = mouse  
Dr = deer  
Rb = rabbit  
Ble = blesbuck (antelope)  
G = Guinea Pig  
S = Sheep

#### Wildlife TRV Derivation Process

- 1) There are at least three results available for two test species within the GRO, REP and MOR effect groups.
- 2) There are three NOAEL results available for calculation of a weighted geometric mean.
- 3) The weighted geometric mean of the adjusted NOAELs for REP and GRO results equals 0.80 mg dieldrin/kg BW/day.
- 4) The weighted geometric mean NOAEL is slightly lower than the lowest LOAEL for mortality at 0.89 mg dieldrin/kg BW/day.
- 5) The mammalian wildlife TRV for dieldrin is equal to 0.80 mg dieldrin/kg BW/day

- 2) There are at least three NOAEL results available for GRO or REP to calculate a weighted geometric mean.
- 3) The NOAEL values are first adjusted based on their respective data evaluation score.

$$\text{Adjusted NOAEL} = \text{NOAEL} * (\text{Data Evaluation Score} / 100)$$

- 4) The weighted geometric mean of the adjusted NOAEL values is calculated as presented in Table 5.3 according to the following equation:

$$\log (\text{GeoMean}) = \{ \text{score}(1) * \log (\text{adj. NOAEL}(1)) + \dots + \text{score} (n) * \log (\text{adj. NOAEL}(n)) \} / \{\text{sum of scores}\}$$

- 5) The weighted geometric mean NOAEL is lower than the lowest LOAEL for mortality.
- 6) The mammalian wildlife TRV for dieldrin is equal to the 0.80 mg /kg BW/day.

<b>Table 5.3</b> <b>Mammalian TRV Derivation for Dieldrin Weighted Geometric Mean of Adjusted NOAELs</b>					
Test ID	NOAELs	Scores	Adjusted NOAEL Value	Weight	Weight*Log Adj NOAEL
988-Dld-Harr -ML-FD-1-REP-1	0.054	91	0.05	91	-119.32
1056-Dld-Murph-ML-FD-1-REP-4	0.14	87	0.1	87	-79.01
1143-Dld-Virgo-ML-FD-1-REP-1	0.34	84	0.3	84	-46.00
1142-Dld-Virgo-ML-FD-1-REP-3	0.65	84	0.5	84	-22.30
978-Dld-Good -ML-FD-1-REP-2	0.66	69	0.5	69	-23.40
1056-Dld-Murph-ML-FD-1-REP-3	0.69	74	0.5	74	-21.81
932-Dld-Chern-ML-GV-1-REP-2	1.5	92	1.4	92	12.87
936-Dld-Coste-ML-GV-1-REP-1	2.0	77	1.5	77	14.44
972-Dld-Gelle-ML-GV-1-REP-3	3.0	86	2.6	86	35.40
953-Dld-Dix-ML-GV-1-REP-1	4.0	77	3.1	77	37.62
1146-Dld-Walke-ML-OR-2-GRO-5	0.05	75	0.0	75	-106.95
1146-Dld-Walke-ML-FD-1-GRO-2	0.79	80	0.6	80	-15.90
1023-Dld-Kolaj-ML-FD-1-GRO-2	1.3	75	1.0	75	-1.59
1023-Dld-Kolaj-ML-FD-2-GRO-2	1.3	75	1.0	75	-1.59
1027-Dld-Krish-ML-FD-1-GRO-4	1.6	69	1.1	69	2.83
932-Dld-Chern-ML-GV-1-GRO-4	3.0	90	2.7	90	38.82
953-Dld-Dix-ML-GV-1-GRO-2	4.0	84	3.4	84	44.21
1020-Dld-Kimbr-ML-FD-1-GRO-1	5.3	77	4.1	77	47.22
1016-Dld-Jones-ML-FD-1-GRO-2	8.0	74	5.9	74	57.15
Sum				1520	-147
(Sum of weight*log (adj NOAEL) / Sum of Weights					-0.10
Weighted Geometric Mean					0.80

#### **5.4 Avian Dieldrin TRV**

The NOAEL and LOAEL values for results with data evaluation scores above 65 are plotted on Figure 5.2 for dieldrin. The following steps were completed to identify a TRV.

- 1) There are at least three results available for growth (GRO), reproduction (REP) or mortality (MOR) endpoints for at least two test species. There is enough data to derive a TRV.
- 2) There are at least three NOAEL results available for GRO or REP to calculate a weighted geometric mean.
- 3) The NOAEL values are first adjusted based on their respective data evaluation score.

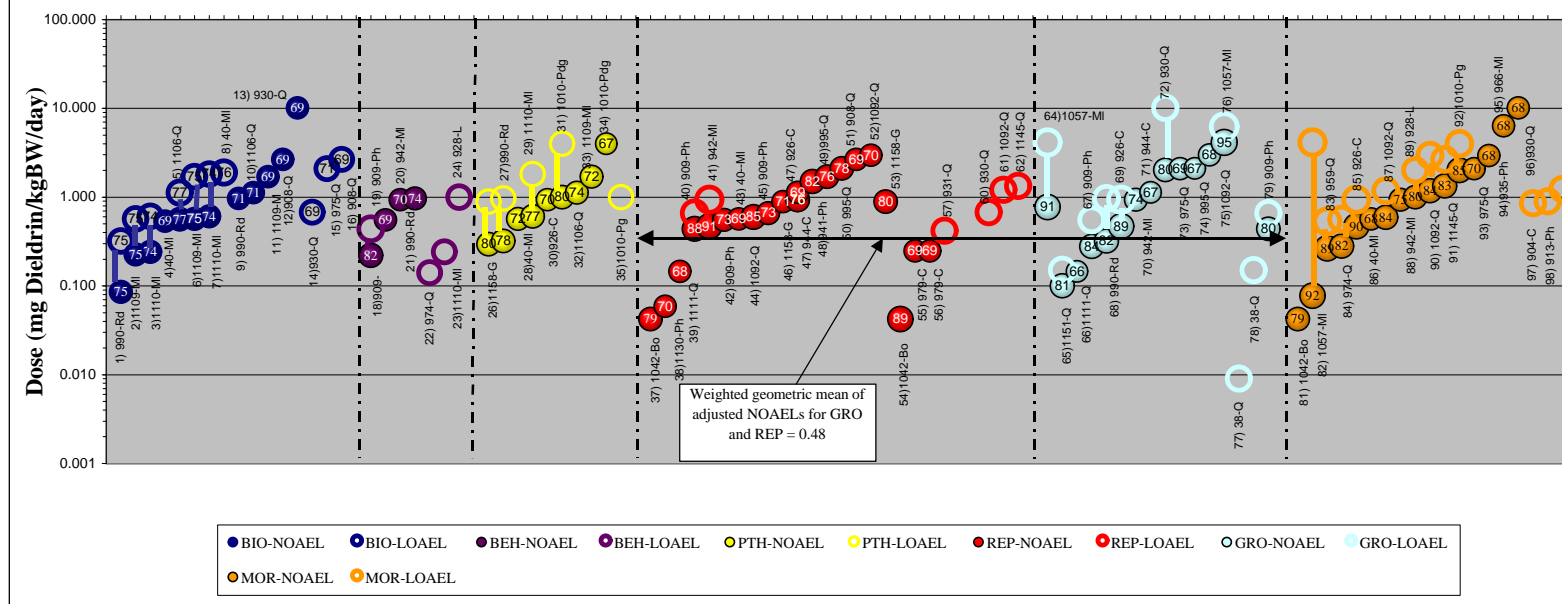
$$\text{Adjusted NOAEL} = \text{NOAEL} * (\text{Data Evaluation Score} / 100)$$

- 4) The weighted geometric mean of the adjusted NOAEL values is calculated as presented in Table 5.4 according to the following equation:

$$\log (\text{GeoMean}) = \{ \text{score}(1) * \log (\text{adj. NOAEL}(1)) + \dots + \text{score} (n) * \log (\text{adj. NOAEL}(n)) \} / \{\text{sum of scores}\}$$

- 5) The weighted geometric mean NOAEL is lower than the lowest LOAEL for mortality.
- 6) The avian wildlife TRV for dieldrin is equal to the 0.48 mg /kg BW/day.

Figure 5.2 Avian TRV Derivation for Dieldrin



Result number → 1) 10 - C  
Reference Number → Test Species

**Test Species Key**

MI = mallard	Ph = pheasant	G = guinea fowl
Q = quail	L = loggerhead shrike	C = chicken
Rd = ring dove	Bo = barn owl	Pdg = pigeon

### Wildlife TRV Derivation Process

- 1) There are at least three results available for two test species within the GRO, REP and MOR effect groups.
- 2) There are three NOAEL results available for calculation of a weighted geometric mean.
- 3) The weighted geometric mean of the adjusted NOAELs for REP and GRO results equals 0.48 mg dieldrin/kg BW/day.
- 4) The weighted geometric mean NOAEL is less than the lowest LOAEL for mortality.
- 5) The avian wildlife TRV for dieldrin is equal to 0.48 mg dieldrin/kg BW/day



Table 5.4 Avian TRV Derivation for Dieldrin Weighted Geometric Mean of Adjusted NOAELs					
Test ID	NOAELs	Scores	Adjusted NOAEL Value	Weight	Weight*Log Adj NOAEL
1042-Dld-Mend-AV-FD-1-REP-2	0.042	80	0.03	80	-116.62
1130-Dld-Strom-AV-FD-1-REP-2	0.06	70	0.0	70	-97.01
1111-Dld-Shell-AV-FD-1-REP-3	0.145	68	0.1	68	-68.37
909-Dld-Atkin-AV-OR-2-REP-6	0.4	88	0.4	88	-36.33
942-Dld-Davis-AV-FD-1-REP-6	0.47	91	0.4	91	-33.78
909-Dld-Atkin-AV-OR-1-REP-4	0.55	73	0.4	73	-28.66
40-Dld-Davis-AV-FD-1-REP-6	0.57	69	0.4	69	-28.20
1092-Dld-Readi-AV-FD-2-REP-6	0.60	85	0.5	85	-25.15
909-Dld-Atkin-AV-OR-2-REP-5	0.66	73	0.5	73	-23.21
1158-Dld-Wiese-AV-FD-1-REP-4	0.9	71	0.6	71	-14.24
926-Dld-Brown-AV-FD-1-REP-4	0.93	76	0.7	76	-11.29
942-Dld-Davis-AV-FD-1-REP-5	0.9	76	0.7	76	-11.45
944-Dld-Davis-AV-FD-1-REP-2	1.13	69	0.8	69	-7.36
941-Dld-Dahlg-AV-OR-1-REP-1	1.50	82	1.2	82	7.35
995-Dld-Hill-AV-FD-1-REP-1	1.70	76	1.3	76	8.44
995-Dld-Hill-AV-FD-1-REP-3	2.1	78	1.6	78	16.72
908-Dld-Anduj-AV-FD-1-REP-4	2.67	69	1.8	69	18.27
1092-Dld-Readi-AV-FD-1-REP-5	3.0	70	2.1	70	22.13
1158-Dld-Wiese-AV-FD-1-REP-3	0.89	80	0.7	80	-11.89
1042-Dld-Mend-AV-FD-1-REP-1	0.04	90	0.0	90	-126.78
979-Dld-Grave-AV-FD-1-REP-2	0.25	69	0.2	69	-53.04
1057-Dld-Nebek-AV-FD-1-GRO-2	0.77	91	0.7	91	-13.89
1151-Dld-Watki-AV-OR-1-GRO-3	0.10	81	0.1	81	-88.41
1111-Dld-Shell-AV-FD-1-GRO-1	0.15	66	0.1	66	-67.22
909-Dld-Atkin-AV-OR-1-GRO-2	0.28	84	0.2	84	-53.14
990-Dld-Heinz-AV-FD-1-GRO-2	0.32	82	0.3	82	-47.76
926-Dld-Brown-AV-FD-1-GRO-2	0.47	89	0.4	89	-33.91
942-Dld-Davis-AV-FD-1-GRO-2	0.93	74	0.7	74	-11.84
944-Dld-Davis-AV-FD-1-GRO-3	1.13	67	0.8	67	-8.01
930-Dld-Call-AV-FD-1-GRO-3	2.02	80	1.6	80	16.70
975-Dld-Gille-AV-FD-1-GRO-2	2.09	69	1.4	69	11.03
995-Dld-Hill-AV-FD-1-GRO-2	2.10	67	1.4	67	9.94
1092-Dld-Readi-AV-FD-2-GRO-2	2.98	68	2.0	68	20.82
1057-Dld-Nebek-AV-FD-1-GRO-3	4.12	95	3.9	95	56.34
909-Dld-Atkin-AV-OR-2-GRO-2	0.44	80	0.4	80	-36.34
Sum				2694	-866
(Sum of weight*log (adj NOAEL) / Sum of Weights					-0.32
Weighted Geometric Mean					0.48

## 4.5 Dieldrin Wildlife TRV References

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## **6.0 RDX**

### **6.1 Literature Search, Retrieval and Review**

The electronic literature search for dieldrin toxicity data was completed according to the procedures provided in Exhibit 4-1. The search results are reported as four separate lists. The first list contains studies identified during the electronic search that were rejected for use based on a review of the abstract and title. This list is included as Attachment A to this appendix. The second list reports the literature for which useful toxicological data was identified and extracted (literature used). The third list reports the literature that was retrieved, reviewed and then rejected (literature rejected). The fourth list contains literature identified in the search that either could not be retrieved for review or has not been received for review (literature pending). These references are listed as Section 6.5.

Each of the citations in these lists are identified with a unique record number assigned as part of the data extraction process as described in Appendix 4-3 (SOP #2). Citations on the “literature not coded” list are labeled with respective literature rejection criteria also described in Appendix 4-3 (SOP #2).

### **6.2 Data Review and Evaluation**

#### ***Mammalian Data***

Data was extracted from seven studies for derivation of the mammalian TRV for RDX. The data reviewed and extracted from these studies is summarized in Table 5.1.

#### ***Avian Data***

The literature search did not identify any toxicity studies for RDX and birds. An avian TRV for RDX could not be derived.

### **6.3 Mammalian RDX TRV**

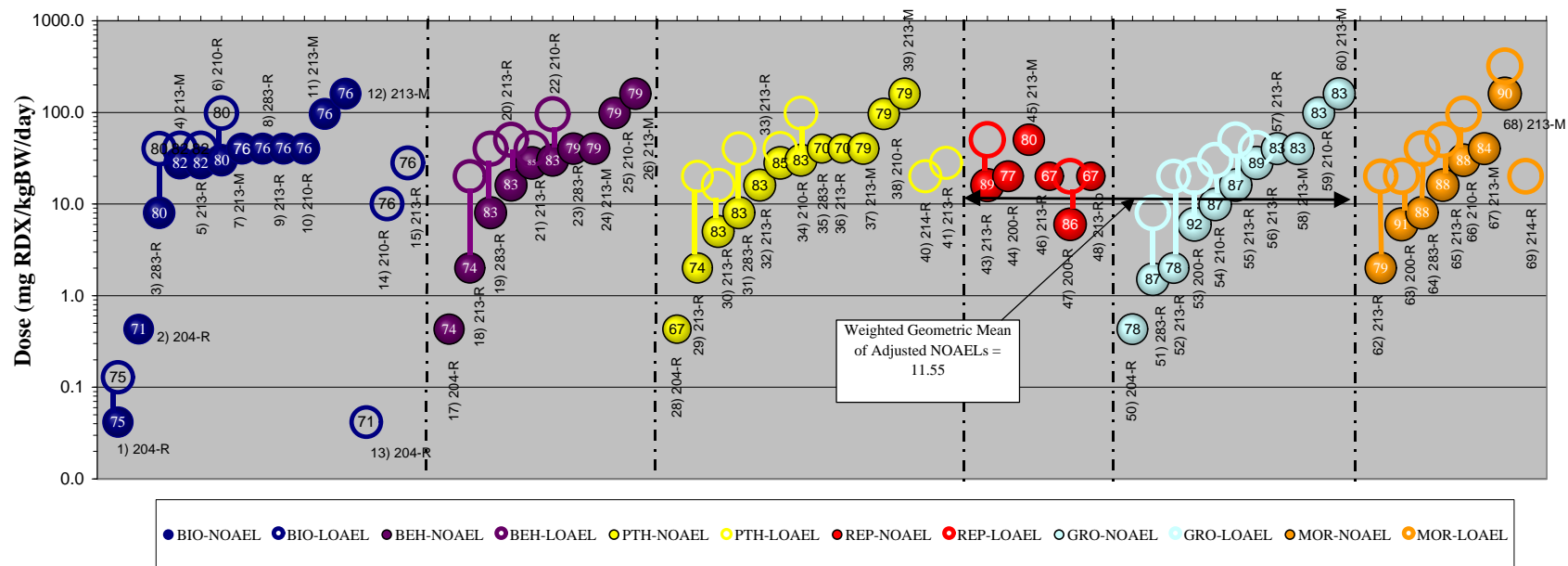
The NOAEL and LOAEL values for results with data evaluation scores above 65 are plotted on Figure 5.1 for dieldrin. The following steps were completed to identify a TRV.

- 1) There are at least three results available for growth (GRO), reproduction (REP) or mortality (MOR) endpoints for at least two test species. There is enough data to derive a TRV.
- 2) There are at least three NOAEL results available for GRO or REP to calculate a weighted geometric mean.

Table 6.1 Mammalian Toxicity Data For RDX

TEST INFORMATION			RE INFORMATION										EFFECT INFORMATION AND EVALUATION SCORES																		
Result #	Reference Number	Test ID	Species	# of Conc/ Doses	Reported Conc/Dose Units	Method of Analyses	Route of Exposure	Exposure Duration	Duration Units	Age	Age Units	Lifespan	Sex	General Effect Group	Effect Type	Effect Measure	Response Site	NOAEL Dose (mg/kg/day)	LOAEL Dose (mg/kg/day)	Data Source	Dose Route	Test Substance Concentrations	Chemical form	Dose Quantification	Endpoint	Dose Range	Statistical Power	Exposure Duration	Test Conditions	Total	
1	204	204-RDX-Hart.-ML-FD-1-BIO-3	Rat	4	mg/kg	U	FD	104	w	NR	NR	NR	BH	BIO	CHM	CHLR	SR	0.04	0.13	10	10	5	10	7	1	8	10	10	4	75	
2	204	204-RDX-Hart.-ML-FD-1-BIO-5	Rat	4	mg/kg	U	FD	104	w	NR	NR	NR	BH	BIO	CHM	RBCE	BL	0.43		10	10	5	10	7	1	4	10	10	4	71	
3	283	283-RDX-Levin-ML-FD-BIO-6	Rat	5	mg/kg/d	M	FD	104	w	3.5	w	NR	M	BIO	CHM	HMGL	BL	8.0	40	10	10	10	10	7	1	8	10	10	4	80	
4	213	213-RDX-Chola-ML-FD-BIO-17	Mouse	6	mg/kg/d	M	FD	13	w	2	m	NR	F	BIO	CHM	EOSN	BL	28	40	10	10	10	10	7	1	10	10	10	4	82	
5	213	213-RDX-Chola-ML-FD-BIO-5	Rat	6	mg/kg/d	M	FD	13	w	3	m	NR	BH	BIO	CHM	HMCT	BL	28	40	10	10	10	10	7	1	10	10	10	4	82	
6	210	210-RDX-Levin-ML-FD-BIO-7	Rat	6	mg/kg/d	M	FD	13	w	6.5	w	NR	F	BIO	CHM	HMGL	BL	30	98	10	10	10	10	7	1	8	10	10	4	80	
7	213	213-RDX-Chola-ML-FD-BIO-18	Mouse	6	mg/kg/d	M	FD	13	w	2	m	NR	BH	BIO	CHM	ERTH	BL	40		10	10	10	10	7	1	4	10	10	4	76	
8	283	283-RDX-Levin-ML-FD-BIO-7	Rat	5	mg/kg/d	M	FD	104	w	3.5	w	NR	BH	BIO	CHM	MCPV	BL	40		10	10	10	10	7	1	4	10	10	4	76	
9	213	213-RDX-Chola-ML-FD-BIO-6	Rat	6	mg/kg/d	M	FD	13	w	3	m	NR	BH	BIO	CHM	MCPV	BL	40		10	10	10	10	7	1	4	10	10	4	76	
10	213	213-RDX-Chola-ML-FD-BIO-19	Mouse	6	mg/kg/d	M	FD	13	w	2	m	NR	BH	BIO	ENZ	GPTR	SR	40		10	10	10	10	7	1	4	10	10	4	76	
11	210	210-RDX-Levin-ML-FD-BIO-8	Rat	6	mg/kg/d	M	FD	13	w	6.5	w	NR	BH	BIO	CHM	HMCT	BL	96		10	10	10	10	7	1	4	10	10	4	76	
12	213	213-RDX-Chola-ML-FD-BIO-24	Mouse	4	mg/kg/d	M	FD	13	w	2	m	NR	BH	BIO	CHM	ERTH	BL	160		10	10	10	10	7	1	4	10	10	4	76	
13	204	204-RDX-Hart.-ML-FD-1-BIO-4	Rat	4	mg/kg	U	FD	104	w	NR	NR	NR	BH	BIO	CHM	SODI	SR		0.04	10	10	5	10	7	1	4	10	10	4	71	
14	210	210-RDX-Levin-ML-FD-BIO-6	Rat	6	mg/kg/d	M	FD	13	w	6.5	w	NR	F	BIO	CHM	LEUK	BL	10		10	10	10	10	7	1	4	10	10	4	76	
15	213	213-RDX-Chola-ML-FD-BIO-7	Rat	6	mg/kg/d	M	FD	13	w	3	m	NR	M	BIO	ENZ	GPTR	SR	28		10	10	10	10	7	1	4	10	10	4	76	
16																															
17	204	204-RDX-Hart.-ML-FD-1-BEH-2	Rat	4	mg/kg	U	FD	104	w	NR	NR	NR	BH	BEH	FDB	FCNS	WO	0.43		10	10	5	10	7	4	4	10	10	4	74	
18	213	213-RDX-Chola-ML-FD-BEH-30	Rat	4	mg/kg/d	U	FD	20	d	2	m	NR	F	BEH	FDB	FCNS	WO	2.0	20	10	10	10	10	5	7	4	8	10	6	74	
19	283	283-RDX-Levin-ML-FD-BEH-4	Rat	5	mg/kg/d	M	FD	104	w	3.5	w	NR	M	BEH	FDB	FCNS	WO	8.0	40	10	10	10	10	7	4	8	10	10	4	83	
20	213	213-RDX-Chola-ML-FD-BEH-36	Rat	4	mg/kg/d	M	FD	13	w	2	m	NR	BH	BEH	FDB	FCNS	WO	16	50	10	10	10	10	7	4	8	10	10	4	83	
21	213	213-RDX-Chola-ML-FD-BEH-3	Rat	6	mg/kg/d	M	FD	13	w	3	m	NR	M	BEH	FDB	FCNS	WO	28	40	10	10	10	10	7	4	10	10	10	4	85	
22	210	210-RDX-Levin-ML-FD-BEH-4	Rat	6	mg/kg/d	M	FD	13	w	6.5	w	NR	M	BEH	FDB	FCNS	WO	30	95	10	10	10	10	7	4	8	10	10	4	83	
23	283	283-RDX-Levin-ML-FD-BEH-5	Rat	5	mg/kg/d	M	FD	104	w	3.5	w	NR	F	BEH	FDB	FCNS	WO	40		10	10	10	10	7	4	4	10	10	4	79	
24	213	213-RDX-Chola-ML-FD-BEH-15	Mouse	6	mg/kg/d	M	FD	13	w	2	m	NR	BH	BEH	FDB	FCNS	WO	40		10	10	10	10	7	4	4	10	10	4	79	
25	210	210-RDX-Levin-ML-FD-BEH-5	Rat	6	mg/kg/d	M	FD	13	w	6.5	w	NR	F	BEH	FDB	FCNS	WO	98		10	10	10	10	7	4	4	10	10	4	79	
26	213	213-RDX-Chola-ML-FD-BEH-22	Mouse	4	mg/kg/d	M	FD	13	w	2	m	NR	BH	BEH	FDB	FCNS	WO	160		10	10	10	10	7	4	4	10	10	4	79	
27																															
28	204	204-RDX-Hart.-ML-FD-1-PTH-8	Rat	4	mg/kg	U	FD	104	w	NR	NR	NR	BH	PTH	ORWT	ORWT	AR	0.43		10	10	5	10	7	4	4	3	10	4	67	
29	213	213-RDX-Chola-ML-FD-PTH-31	Rat	4	mg/kg/d	U	FD	20	d	2	m	NR	F	PTH	ORWT	ORWT	LI	2.0	20	10	10	10	10	5	7	4	8	10	6	74	
30	213	213-RDX-Chola-ML-FD-PTH-37	Rat	4	mg/kg/d	M	FD	13	w	2	m	NR	BH	PTH	ORWT	ORWT	KI	5.0	16	10	10	10	10	7	4	8	10	10	4	83	
31	283	283-RDX-Levin-ML-FD-PTH-9	Rat	5	mg/kg/d	M	FD	104	w	3.5	w	NR	M	PTH	HIS	NCRO	KI	8.0	40	10	10	10	10	7	4	8	10	10	4	83	
32	213	213-RDX-Chola-ML-FD-PTH-38	Rat	4	mg/kg/d	M	FD	13	w	2	m	NR	BH	PTH	ORWT	ORWT	BR	16		10	10	10	10	7	4	8	10	10	4	83	
33	213	213-RDX-Chola-ML-FD-PTH-10	Rat	6	mg/kg/d	M	FD	13	w	3	m	NR	BH	PTH	ORWT	ORWT	HE	28	40	10	10	10	10	7	4	10	10	10	4	85	
34	210	210-RDX-Levin-ML-FD-PTH-10	Rat	6	mg/kg/d	M	FD	13	w	6.5	w	NR	F	PTH	ORWT	SMIX	LI	30	98	10	10	10	10	7	4	8	10	10	4	83	
35	283	283-RDX-Levin-ML-FD-PTH-10	Rat	5	mg/kg/d	M	FD	104	w	3.5	w	NR	BH	PTH	HIS	GHIS	WO	40		10	10	10	10	7	4	4	1	10	4	70	
36	213	213-RDX-Chola-ML-FD-PTH-13	Rat	6	mg/kg/d	M	FD	13	w	3	m	NR	BH	PTH	HIS	GHIS	WO	40		10	10	10	10	7	4	4	1	10	4	70	
37	213	213-RDX-Chola-ML-FD-PTH-20	Mouse	6	mg/kg/d	M	FD	13	w	2	m	NR	BH	PTH	ORWT	ORWT	LI	40		10	10	10	10	7	4	4	10	10	4	79	
38	210	210-RDX-Levin-ML-FD-PTH-11	Rat	6	mg/kg/d	M	FD	13	w	6.5	w	NR	BH	PTH	ORWT	ORWT	BR	96		10	10	10	10	7	4	4	10	10	4	79	
39	213	213-RDX-Chola-ML-FD-PTH-27	Mouse	4	mg/kg/d	M	FD	13	w	2	m	NR	BH	PTH	HIS	GHIS	WO	160		10	10	10	10	7	4	4	10	10	4	79	
40	214	214-RDX-Schne-ML-GV-PTH-2	Rat	2	mg/kg	M	GV	90	d	NR	NR	NR	BH	PTH	HIS	HEMR	LU	20		10	8	10	10	10	4	4	10	10	4	80	
41	213	213-RDX-Chola-ML-FD-PTH-12	Rat	6	mg/kg/d	M	FD	13	w	3	m	NR	M	PTH	ORWT	ORWT	BR	28		10	10	10	10	7	4	4	10	10	4	79	
42																															
43	213	213-RDX-Chola-ML-FD-REP-37	Rat	4	mg/kg/d	M	FD	13	w	2	m	NR	F	REP	REP	RSUC	WO	16	50	10	10	10	10	7	10	8	10	10	4	89	
44	200	200-RDX-USAEH-ML-OR-REP-1	Rat	4	mg/kg/d	M	OR	9	d	10	w	NR	F	REP	REP	REP	WO	20		10	8	10	10	10	10	4	1	10	4	77	
45	213	213-RDX-Chola-ML-FD-REP-28	Mouse	4	mg/kg/d	U	FD	13	w	2	m	NR	M	REP	REP	SPCV	SM	50		10	10	10	10	5	7	10	4	10	10	4	80
46	213	213-RDX-Chola-ML-FD-REP-32	Rat	4	mg/kg/d	U	FD	20	d	2	m	NR	F	REP	REP	FERT	WO	20		10	10	10	10	5	7	10	4	1	6	4	67
47	200	200-RDX-USAEH-ML-OR-REP-2	Rat	4	mg/kg BW	M	OR	9	d	10	w	NR	F	REP	REP	PRWT	WO	6.0	20	10	8	10	10	10	10	4	10	10	4	86	
48	213	213-RDX-Chola-ML-FD-REP	Rabbit	4	mg/kg/d	U	FD	20	d	2	m	NR	F	REP	REP	FERT	WO	20		10	10	10	10	5	7	10	4	1	6	4	67
49																															
50	204	204-RDX-Hart.-ML-FD-1-GRO-1	Rat	4	mg/kg	U	FD	104	w																						

Figure 6.1 Mammalian TRV Derivation for RDX



Result number → 1) 10 - C  
Reference Number →  
Test Species →

**Test Species Key**

R = rat  
M = mouse  
Rb = rabbit

- 3) The NOAEL values are first adjusted based on their respective data evaluation score.

$$\text{Adjusted NOAEL} = \text{NOAEL} * (\text{Data Evaluation Score} / 100)$$

- 4) The weighted geometric mean of the adjusted NOAEL values is calculated as presented in Table 6.2 according to the following equation:

$$\log (\text{GeoMean}) = \{ \text{score}(1) * \log (\text{adj. NOAEL}(1)) + \dots + \text{score} (n) * \log (\text{adj. NOAEL}(n)) \} / \{ \text{sum of scores} \}$$

- 5) The weighted geometric mean NOAEL is lower than the lowest LOAEL for mortality.
- 6) The mammalian wildlife TRV for RDX is equal to the 11.55 mg /kg BW/day.

Table 6.2 Mammalian TRV Derivation for RDX Weighted Geometric Mean of Adjusted NOAELs					
Test ID	NOAELs	Scores	Adjusted NOAEL Value	Weight	Weight*Log Adj NOAEL
204-RDX-Hart.-ML-FD-1-GRO-1	0.43	78	0.34	78	-37.04
283-RDX-Levin-ML-FD-GRO-2	1.5	87	1.3	87	10.06
213-RDX-Chola-ML-FD-GRO-29	2.0	78	1.6	78	15.06
200-RDX-USAEH-ML-OR-REP-2	6.0	86	5.2	86	61.29
200-RDX-USAEH-ML-OR-GRO-3	6.0	90	5.4	90	65.92
210-RDX-Levin-ML-FD-GRO-2	9.9	87	8.6	87	81.36
213-RDX-Chola-ML-FD-REP-37	16	89	14.2	89	102.66
213-RDX-Chola-ML-FD-GRO-35	16	87	13.9	87	99.50
200-RDX-USAEH-ML-OR-REP-1	20	77	15.4	77	91.44
213-RDX-Chola-ML-FD-REP-32	20	67	13.4	67	75.52
213-RDX-Chola-ML-FD-REP	20	67	13.4	67	75.52
213-RDX-Chola-ML-FD-GRO-1	28	89	24.9	89	124.29
213-RDX-Chola-ML-FD-GRO-2	40	83	33.2	83	126.25
213-RDX-Chola-ML-FD-GRO-14	40	83	33.2	83	126.25
213-RDX-Chola-ML-FD-REP-28	50	80	40.0	80	128.16
210-RDX-Levin-ML-FD-GRO-3	98	83	81.3	83	158.56
213-RDX-Chola-ML-FD-GRO-21	160	83	132.8	83	176.23
Sum				1394	1481
(Sum of weight*log (adj NOAEL) / Sum of Weights					1.06
Weighted Geometric Mean					11.55

## **6.4 Avian RDX TRV**

The literature search completed for RDX (Exhibit 4-1) did not identify any studies of RDX and avian test species. An avian TRV for RDX could not be derived.

## **6.5 RDX Wildlife TRV References**

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